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Prior Authorization Guideline

Guideline Name	Actemra (tocilizumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Actemra (tocilizumab SC)
<p>Rheumatoid arthritis (RA) Indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDs).</p> <p>Systemic Juvenile Idiopathic Arthritis (SJIA) Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.</p> <p>Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.</p> <p>Giant Cell Arteritis (GCA) Indicated for the treatment of giant cell arteritis (GCA) in adult patients.</p> <p>Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) Indicated for slowing the rate of decline in pulmonary function in adult patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).</p>

2 . Criteria

Product Name: Actemra SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active rheumatoid arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none"> • methotrexate • leflunomide • sulfasalazine <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*</p> <ul style="list-style-type: none"> • Cimzia (certolizumab pegol) • Enbrel (etanercept) • Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm • Rinvoq (upadacitinib) • Simponi (golimumab) • Xeljanz/XR (tofacitinib/ER) 	

OR

4.2 For continuation of prior Actemra therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Actemra SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline	

Product Name: Actemra SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of active systemic juvenile idiopathic arthritis	

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of systemic glucocorticoid (e.g., prednisone)

Product Name: Actemra SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [4]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline	

Product Name: Actemra SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active polyarticular juvenile idiopathic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:</p> <ul style="list-style-type: none"> • leflunomide • methotrexate <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*</p> <ul style="list-style-type: none"> • Enbrel (etanercept) • Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm • Xeljanz (tofacitinib) <p style="text-align: center;">OR</p> <p>4.2 For continuation of Actemra therapy, defined as no more than a 45-day gap in therapy</p>	
Notes	* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Actemra SC

Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Actemra SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of giant cell arteritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to a glucocorticoid</p>	

Product Name: Actemra SC

Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

Product Name: Actemra SC	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:</p> <p>1.1 Exclusion of other known causes of interstitial lung disease (ILD)</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following:</p> <p>1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD</p> <p style="text-align: center;">OR</p> <p>1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD</p>	

AND

2 - Prescribed by or in consultation with a pulmonologist or rheumatologist

Product Name: Actemra SC	
Diagnosis	Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
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5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
6. Khanna D, Lin CJF, Furst DE, et al. Tocilizumab in systemic sclerosis: a randomized, double-blind, placebo-controlled, phase 3 trial. *Lancet Respir Med.* 2020;8:963–74.
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8. UpToDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: <https://www.uptodate.com>. Accessed April 11, 2021.

Actimmune (interferon gamma-1b)

Prior Authorization Guideline

Guideline Name	Actimmune (interferon gamma-1b)
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Actimmune (interferon gamma-1b)
Chronic Granulomatous Disease (CGD) Indicated for reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD).
Severe Malignant Osteopetrosis (SMO) Indicated for delaying time to disease progression in patients with severe, malignant osteopetrosis (SMO).

2 . Criteria

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of one of the following:

- Chronic granulomatous disease (CGD)
- Severe, malignant osteopetrosis (SMO)

Product Name: Actimmune	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Actimmune Prescribing Information. Horizon Therapeutics USA, Inc. Deerfield, IL. March 2021.

Prior Authorization Guideline

Guideline Name	Adalimumab
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Guideline Note:

Effective Date:	3/1/2024
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Note:

This guideline applies to the following Tier 2 products: Humira, Cyltezo, Brand Adalimumab-adbm, and Hadlima. For nonpreferred biosimilars, refer to the "Managed Administrative Biosimilars Policy" guideline for review.

1 . Indications

Drug Name: Humira (adalimumab)
Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage and improving physical function in adult patients with moderately to severe active rheumatoid arthritis (RA). Humira can be used alone or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs (DMARDs).
Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 years of age and older. Humira can be used alone or in combination with MTX.
Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Humira can be used alone or in combination with non-biologic DMARDs.
Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe

chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Humira should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older. Limitations of use: The effectiveness of Humira has not been established in patients who have lost response to or were intolerant to TNF blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

Drug Name: Cyltezo (adalimumab-adbm), Adalimumab-adbm, Hadlima (adalimumab-bwwd)

Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Can be used alone or in combination with methotrexate.

Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative

colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

2 . Criteria

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active RA</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none"> • methotrexate • leflunomide • sulfasalazine 	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severely active PJIA</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p>	

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

Notes

* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Notes

* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis Psoriatic Arthritis (PsA)

Approval Length 6 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [5]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Notes

* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis

Psoriatic Arthritis (PsA)

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Notes

* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe chronic plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [6]:</p> <ul style="list-style-type: none"> • Greater than or equal to 3% body surface area involvement • Severe scalp psoriasis • Palmoplantar (i.e., palms, soles), facial, or genital involvement <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:</p> <ul style="list-style-type: none"> • corticosteroids (e.g., betamethasone, clobetasol) • vitamin D analogs (e.g., calcitriol, calcipotriene) • tazarotene • calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • anthralin • coal tar <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a dermatologist</p>	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:</p> <ul style="list-style-type: none"> • Reduction the body surface area (BSA) involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline 	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p>	

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL
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Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL
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Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis	Crohn's disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - One of the following [9, 10]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [9, 10]

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL
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Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Crohn's disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 9, 10]:	

<ul style="list-style-type: none"> Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline Reversal of high fecal output state 	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [11, 12]:</p> <ul style="list-style-type: none"> Greater than 6 stools per day Frequent blood in the stools Frequent urgency Presence of ulcers Abnormal lab values (e.g., hemoglobin, ESR, CRP) Dependent on, or refractory to, corticosteroids <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [11, 12]</p> <ul style="list-style-type: none"> 6-mercaptopurine Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine) Azathioprine 	

<ul style="list-style-type: none"> Corticosteroids (e.g., prednisone) <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a gastroenterologist</p>	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy</p> <p style="text-align: center;">OR</p> <p>1.2 For patients who have been maintained on Humira therapy for longer than 12 weeks, documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 11, 12]:</p> <ul style="list-style-type: none"> Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline Reversal of high fecal output state 	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*

Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a dermatologist</p>	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Uveitis (UV)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-infectious uveitis

AND

2 - Uveitis is classified as one of the following:

- intermediate
- posterior
- panuveitis

AND

3 - Prescribed by or in consultation with one of the following:

- ophthalmologist
- rheumatologist

Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL
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Product Name: Humira*, Cyltezo*, Brand Adalimumab-adbm*, Hadlima*	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	
Notes	* If patient meets criteria above, please approve at GPI list BSWCOM ADAL

3 . References

1. Humira Prescribing Information. Abbvie Inc. North Chicago, IL. February 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol* 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113:481-517.
10. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology.* 2021;160(7):2496-2508.
11. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413.
12. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol.* 2020;158:1450-1461.
13. Hadlima Prescribing Information. Samsung Bioepis Co, Ltd; Organon LLC. Jersey City, NJ. July 2023.
14. Cyltezo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.

Adbry (tralokinumab-ldrm)

Prior Authorization Guideline

Guideline Name	Adbry (tralokinumab-ldrm)
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Guideline Note:

Effective Date:	12/1/2022
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1 . Indications

Drug Name: Adbry (tralokinumab-ldrm)
Atopic Dermatitis Indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. May be used with or without topical corticosteroids.

2 . Criteria

Product Name: Adbry	
Diagnosis	Atopic Dermatitis
Approval Length	6 Months*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Patient is 18 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream[^]
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment[^]

Notes

*QL Override (For new starts only): Enter 2 PAs as follows: First PA: Approve 6 syringes per 28 days for one month; Second PA: Approve 4 syringes per 28 days (no overrides needed) for the remaining 5 months. (Adbry is hard-coded with a quantity of 4 syringes per 28 days); [^] Product may require step therapy

Product Name: Adbry

Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:</p> <ul style="list-style-type: none"> • Reduction in body surface area involvement from baseline • Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A] 	

3 . Background

Clinical Practice Guidelines			
Table 1. Relative potencies of topical corticosteroids [2]			
Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25

	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

- A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score ($A/5 + 7B/2 + C$) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

5 . References

1. Adbry Prescribing Information. Leo Pharma Inc. Madison, NJ. December 2021.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014; 71(1):116-32.
3. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. *Dermatology*. 1993; 186:23-31.
4. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet* 2017; 389(10086)(suppl):2287-2303.
5. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. *Curr Probl Dermatol*. 2011; 41:149-55.

Addyi (flibanserin)

Prior Authorization Guideline

Guideline Name	Addyi (flibanserin)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Addyi (flibanserin)
Acquired, generalized hypoactive sexual desire disorder (HSDD) Indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD), as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: 1) a co-existing medical or psychiatric condition, 2) problems within the relationship, 3) or the effects of a medication or other drug substance. Acquired HSDD refers to HSDD that develops in a patient who previously had no problems with sexual desire. Generalized HSDD refers to HSDD that occurs regardless of the type of stimulation, situation or partner. Limitations of Use: 1) Addyi is not indicated for the treatment of HSDD in postmenopausal women or in men. 2) Addyi is not indicated to enhance sexual performance.

2 . Criteria

Product Name: Addyi	
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Acquired, generalized hypoactive sexual desire disorder (HSDD) [2-5, A-B] • Female sexual interest/arousal disorder [D] <p style="text-align: center;">AND</p> <p>2 - Symptoms of HSDD or female sexual interest/arousal disorder have persisted for at least 6 months [2-5, A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is premenopausal [2-4]</p> <p style="text-align: center;">AND</p> <p>4 - HSDD is not attributed to one of the following[1]</p> <ul style="list-style-type: none"> • A co-existing medical or psychiatric condition • Problems within a relationship • Effects of a medication or other drug substance 	

Product Name: Addyi	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following:

- Improvement in number of satisfying sexual events from baseline
- Improvement in sexual desire from baseline

AND

2 - Patient continues to be premenopausal

3 . Endnotes

- A. The diagnostic criteria for Hypoactive Sexual Desire Disorder (HSDD) includes: (a) A persistently or recurrently deficient (or absent) sexual/erotic thoughts or fantasies and desire for sexual activity. The judgment of deficiency is made by the clinician, taking into account factors that affect sexual functioning, such as age and general and sociocultural contexts of the individual's life. (b) The symptoms in criterion (a) have persisted for a minimum duration of approximately 6 months. (c) The symptoms in criterion (a) cause clinically significant distress in the individual. (d) The sexual dysfunction is not better explained by a nonsexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance/medication or another medical condition. [5]
- B. In the clinical trials, acquired HSDD was defined as HSDD that developed in patients who previously had no problems with sexual desire. Generalized HSDD was defined as HSDD that was not limited to certain types of stimulation, situations or partners. [1]
- C. Addyi should be discontinued after 8 weeks if the patient does not report an improvement in her symptoms. [1] An additional month is added to the initial authorization duration to allow for patient follow-up with the provider.
- D. The diagnostic category HSDD (DSM-IV) was used in the FDA report and in the associated studies, but is no longer used and has been replaced by the term female sexual interest/arousal disorder (DSM-5). [5-6]

4 . References

1. Addyi Prescribing Information. Sprout Pharmaceuticals, Inc. Raleigh, NC. September 2021.
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4. DeRogatis LR, Komer L, Katz M, et al. Treatment of Hypoactive Sexual Desire Disorder in Premenopausal Women: Efficacy of Flibanserin in the VIOLET Study. *J Sex Med* 2012;9:1074–1085.
5. American Psychiatric Association. Sexual dysfunctions. In: *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed. Arlington, Virginia: American Psychiatric Association; 2013. <https://doi-org.proxy.cc.uic.edu/10.1176/appi.books.9780890425596.dsm13>.
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Aemcolo (rifamycin)

Prior Authorization Guideline

Guideline Name	Aemcolo (rifamycin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Aemcolo (rifamycin)
Travelers' Diarrhea (TD) Indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults. Limitations of use: Aemcolo is not indicated in patients with diarrhea complicated by fever or bloody stool or due to pathogens other than noninvasive strains of Escherichia coli. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Aemcolo and other antibacterial drugs, Aemcolo should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

2 . Criteria

Product Name: Aemcolo	
Approval Length	14 days [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD) [B]

AND

2 - Diarrhea is not accompanied by fever or bloody stool [B]

AND

3 - One of the following:

3.1 Trial and failure to one of the following: [2, C]

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

- Zithromax (azithromycin)
- Cipro (ciprofloxacin)
- Levaquin (levofloxacin)
- Ofloxacin

3 . Endnotes

- A. The recommended dosage of Aemcolo is 388 mg (two tablets) orally twice daily for three days. 14 day approval length allows for sufficient time for the patient to pick up the medication from the pharmacy. [1]
- B. For those who present with uncomplicated travelers' diarrhea (TD), determination of the microbiologic agent is generally unnecessary, but when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. Aemcolo was not shown to be effective in patients with diarrhea complicated by fever and/or bloody stool. The effectiveness of Aemcolo in TD caused by pathogens other than E. coli has not been demonstrated. [1, 2]

- C. According to the Centers for Disease Control and Prevention's Yellow Book, fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of TD. Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. [2, 3]

4 . References

1. Aemcolo prescribing information. Cosmo Technologies, Ltd. San Diego, CA. November 2018.
2. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. *J Travel Med.* 2017;24(suppl 1):S63-S80.
3. Connors BA. Travelers' diarrhea: CDC Health Information for International Travel. Centers for Disease Control and Prevention; 2020. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2018/the-pre-travel-consultation/travelers-diarrhea>. Accessed January 20, 2020.

Prior Authorization Guideline

Guideline Name	Afinitor, Afinitor Disperz (everolimus)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Afinitor (everolimus tablet)
<p>Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET) Indicated for the treatment of progressive PNET in patients with unresectable, locally advanced or metastatic disease. Afinitor is not indicated for the treatment of patients with functional carcinoid tumors.</p> <p>Advanced Renal Cell Carcinoma (RCC) Indicated for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.</p> <p>Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC) Indicated for the treatment of adult patients with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.</p> <p>Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected.</p> <p>Advanced Hormone Receptor-Positive, HER2-Negative Breast Cancer (Advanced HR + BC) Indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane, after failure of treatment with letrozole or anastrozole.</p> <p>Neuroendocrine Tumors of Gastrointestinal or Lung Origin Indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of</p>

gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic. AFINITOR is not indicated for the treatment of patients with functional carcinoid tumors.

Drug Name: Afinitor Disperz (everolimus tablet for oral suspension)

Subependymal Giant Cell Astrocytoma (SEGA) Indicated for the treatment of adult and pediatric patients aged 1 year and older with TSC who have subependymal giant cell astrocytoma (SEGA) that requires therapeutic intervention but cannot be curatively resected. The effectiveness of Afinitor Disperz is based on demonstration of durable objective response, as evidenced by reduction in SEGA tumor volume. Improvement in disease-related symptoms and overall survival in patients with SEGA and TSC has not been demonstrated.

Tuberous Sclerosis Complex (TSC) Associated Partial-onset Seizures Indicated for the adjunctive treatment of adult and pediatric patients aged 2 years and older with TSC-associated partial-onset seizures

2 . Criteria

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Unresectable, locally advanced • Metastatic <p style="text-align: center;">AND</p>	

3 - Both of the following (applies to BRAND Afinitor only):

3.1 Trial and failure or intolerance to generic everolimus tablet

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	
AND	
2 - Both of the following (applies to BRAND Afinitor only):	
2.1 Trial and failure or intolerance to generic everolimus tablet	

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of advanced/metastatic renal cell carcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure with one of the following:*</p> <ul style="list-style-type: none">• Sutent (sunitinib)• Nexavar (sorafenib) <p style="text-align: center;">AND</p> <p>3 - Both of the following (applies to BRAND Afinitor only):</p> <p>3.1 Trial and failure or intolerance to generic everolimus tablet</p>	

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with an oncologist

Notes

*Criterion is part of the FDA-approved label.

Product Name: Brand Afinitor, Generic everolimus tablet

Diagnosis | Advanced Renal Cell Carcinoma

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Both of the following (applies to BRAND Afinitor only):

2.1 Trial and failure or intolerance to generic everolimus tablet

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following (applies to BRAND Afinitor only):</p> <p style="padding-left: 20px;">2.1 Trial and failure or intolerance to generic everolimus tablet</p> <p style="text-align: center;">AND</p> <p style="padding-left: 20px;">2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) <p style="text-align: center;">AND</p>	

3 - Prescribed by or in consultation with a nephrologist

Product Name: Brand Afinitor, Generic everolimus tablet

Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Both of the following (applies to BRAND Afinitor only):

2.1 Trial and failure or intolerance to generic everolimus tablet

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor, Generic everolimus tablet, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension

Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Both of the following (applies to BRAND Afinitor only):

3.1.1 Trial and failure or intolerance to generic everolimus tablet

AND

3.1.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting **ONE** of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

OR

3.2 Both of the following (applies to BRAND Afinitor Disperz only):

3.2.1 Trial and failure or intolerance to generic everolimus tablet for oral suspension

AND

3.2.2 Submission of documentation (e.g. chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet, Brand Afinitor Disperz, Generic everolimus tablet for oral suspension

Diagnosis	Subependymal Giant Cell Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Both of the following (applies to BRAND Afinitor only):

2.1.1 Trial and failure or intolerance to generic everolimus tablet

AND

2.1.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

OR

2.2 Both of the following (applies to BRAND Afinitor Disperz only):

2.2.1 Trial and failure or intolerance to generic everolimus tablet for oral suspension

AND

2.2.2 Submission of documentation (e.g. chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to one of the following:*</p>	

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Both of the following (applies to BRAND Afinitor only):

3.1 Trial and failure or intolerance to generic everolimus tablet

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with an oncologist

Notes	*Criterion is part of the FDA-approved label.
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Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

AND

2 - Both of the following (applies to BRAND Afinitor only):

2.1 Trial and failure or intolerance to generic everolimus tablet

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin	
AND	
2 - One of the following:	
<ul style="list-style-type: none">• Unresectable, locally advanced disease• Metastatic disease	

AND

3 - Both of the following (applies to BRAND Afinitor only):

3.1 Trial and failure or intolerance to generic everolimus tablet

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	
AND	
2 - Both of the following (applies to BRAND Afinitor only):	
2.1 Trial and failure or intolerance to generic everolimus tablet	

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of TSC-associated partial-onset seizures	
AND	
2 - Patient is 2 years of age or older	
AND	
3 - Both of the following (applies to BRAND Afinitor Disperz only):	
3.1 Trial and failure or intolerance to generic everolimus tablet for oral suspension	
AND	

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient shows reduction in seizure frequency while on therapy	
AND	
2 - Both of the following (applies to BRAND Afinitor Disperz only):	
2.1 Trial and failure or intolerance to generic everolimus tablet for oral suspension	
AND	
2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:	
<ul style="list-style-type: none">• Allergic response or intolerance to one of the inactive ingredients of the generic drug	

- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . References

1. Afinitor and Afinitor Disperz Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. February 2022.

Afrezza (insulin human, inhalation powder)

Prior Authorization Guideline

Guideline Name	Afrezza (insulin human, inhalation powder)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Afrezza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of type 1 diabetes mellitus</p> <p style="text-align: center;">AND</p>	

1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)

OR

1.2 Diagnosis of type 2 diabetes mellitus

AND

2 - Unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]

- Physical impairment
- Visual impairment
- Lipohypertrophy

AND

3 - Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Afrezza will NOT be approved in patients:

- Who smoke cigarettes
- Who recently quit smoking (within the past 6 months) [B]
- With chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) [C]

Product Name: Afrezza	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Repeat pulmonary function test confirms that the patient has NOT experienced a decline of 20% or more in FEV1 from baseline [1]</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of positive clinical response to Afrezza therapy</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following: [1]</p> <ul style="list-style-type: none"> • Patient does NOT have chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) • Patient does not smoke cigarettes 	

2 . Endnotes

- A. The inclusion criteria for the phase III trial includes the following parameters: Forced expiratory volume in 1 second (FEV1) = 70% of predicted values. [2, 3]
- B. The exclusion criteria for the phase III trial excludes current smokers or smoking history within the past 6 months. [2, 3]
- C. Afrezza (insulin human) is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD).

3 . References

1. Afrezza prescribing information. MannKind Corporation. Danbury, CT. September 2017.
2. Bode BW, McGill JB, Lorber DL, et al. Inhaled Technosphere Insulin Compared With Injected Prandial Insulin in Type 1 Diabetes: A Randomized 24-Week Trial. Diabetes Care. 2015 Dec;38(12):2266-73.

3. Rosenstock J, Franco D, Korpachev V, et al. Inhaled Technosphere Insulin Versus Inhaled Technosphere Placebo in Insulin-Naïve Subjects With Type 2 Diabetes Inadequately Controlled on Oral Antidiabetes Agents. *Diabetes Care*. 2015 Dec;38(12):2274-81.
4. Per clinical consult with endocrinologist, August 6, 2014.

Prior Authorization Guideline

Guideline Name	Age Limit Exceptions
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Guideline Note:

Effective Date:	1/1/2024
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1 . Criteria

Product Name: Nexium delayed-release packets, Brand Prevacid Solutabs, generic lansoprazole delayed-release orally disintegrating tablets, esomeprazole for delayed release susp packets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - One of the following: 1.1 Both of the following: 1.1.1 Patient is less than 12 years of age AND	

1.1.2 If for brand Nexium delayed release packets, patient has tried and failed or has contraindications or intolerance to 2 formulary agents (unless the patient’s required dose is unavailable in a generic product)

OR

1.2 Both of the following:

1.2.1 Requested drug is for a medically accepted use as defined by FDA approved labeling or “Coverage of off-label Non-FDA approved indications” guideline

AND

1.2.2 One of the following:

1.2.2.1 Trial and failure of all oral formulary alternatives

OR

1.2.2.2 Clinically significant reason why all oral formulary alternatives are not appropriate (If a formulation can be opened and administered by mixing with food or via a feeding tube, clinical justification as to why this method would not be appropriate must be addressed as well)

Product Name: Brand Tazorac, Fabior, Arazlo, Generic tazarotene	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Patient is less than 40 years of age	
OR	

<p>1.2 Both of the following:</p> <p>1.2.1 One of the following:</p> <ul style="list-style-type: none"> • Diagnosis of acne vulgaris (i.e., acne) • Diagnosis of plaque psoriasis <p style="text-align: center;">AND</p> <p>1.2.2 Patient has tried and failed or has contraindications or intolerance to 2 formulary agents (for Arazlo, Fabior, and Tazorac cream 0.1% only)</p>	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion.

Product Name: Brand Vyvanse chewable tablet, Generic lisdexamfetamine chewable tablets, Quillivant XR suspension, Quillichew ER tablets, Generic methylphenidate chewable tablets	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient is less than 12 years of age</p> <p style="text-align: center;">OR</p> <p>1.2 One of the following:</p> <ul style="list-style-type: none"> • Medical condition that causes difficulty swallowing solid dosage formulations • Developmental delay or clinical justification that requires liquid or chewable medications (if a capsule formulation cannot be opened and administered by mixing with specified food or liquid) 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion.

Alecensa (alectinib)

Prior Authorization Guideline

Guideline Name	Alecensa (alectinib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Alecensa (alectinib)
Non-small cell lung cancer Indicated for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

2 . Criteria

Product Name: Alecensa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer	

AND

2 - Prescribed by or in consultation with an oncologist

Notes

*CLIA-certified laboratories: <https://wwwn.cdc.gov/clia/Resources/LabSearch.aspx>

Product Name: Alecensa

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Alecensa prescribing information. Genentech. South San Francisco, CA. September 2021.

Prior Authorization Guideline

Guideline Name	Alfa Interferons
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Intron A (interferon alfa-2b)
<p>Hairy Cell Leukemia Indicated for the treatment of patients 18 years of age or older with hairy cell leukemia.</p> <p>Malignant Melanoma Indicated as adjuvant to surgical treatment in patients 18 years of age or older with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery.</p> <p>Follicular Lymphoma Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkin's Lymphoma in conjunction with anthracycline-containing combination chemotherapy in patients 18 years of age or older. Efficacy of Intron A therapy in patients with low-grade, low-tumor burden follicular Non-Hodgkin's Lymphoma has not been demonstrated.</p> <p>Condylomata Acuminata Indicated for intralesional treatment of selected patients 18 years of age or older with condylomata acuminata involving external surfaces of the genital and perianal areas. The use of this product in adolescents has not been studied.</p> <p>AIDS-Related Kaposi's Sarcoma Indicated for the treatment of selected patients 18 years of age or older with AIDS-Related Kaposi's Sarcoma. The likelihood of response to Intron A therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.</p> <p>Chronic Hepatitis C Indicated for the treatment of chronic hepatitis C in patients 18 years of</p>

age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive. Studies in these patients demonstrated that Intron A therapy can produce clinically meaningful effects on this disease, manifested by normalization of serum alanine aminotransferase (ALT) and reduction in liver necrosis and degeneration. A liver biopsy should be performed to establish the diagnosis of chronic hepatitis. Patients should be tested for the presence of antibody to HCV. Patients with other causes of chronic hepatitis, including autoimmune hepatitis, should be excluded. Prior to initiation of Intron A therapy, the physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis C: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other clinical signs of decompensation - Bilirubin less than or equal to 2 mg/dL - Albumin stable and within normal limits - Prothrombin time less than 3 seconds prolonged - WBC greater than or equal to 3,000/mm³ - Platelets greater than or equal to 70,000/mm³. Serum creatinine should be normal or near normal. Prior to initiation of Intron A therapy, CBC and platelet counts should be evaluated in order to establish baselines for monitoring potential toxicity. These tests should be repeated at Weeks 1 and 2 following initiation of Intron A therapy, and monthly thereafter. Serum ALT should be evaluated at approximately 3-month intervals to assess response to treatment. Patients with preexisting thyroid abnormalities may be treated if thyroid-stimulating hormone (TSH) levels can be maintained in the normal range by medication. TSH levels must be within normal limits upon initiation of Intron A treatment and TSH testing should be repeated at 3 and 6 months. Intron A in combination with Rebetol is indicated for the treatment of chronic hepatitis C in patients 3 years of age and older with compensated liver disease previously untreated with alpha interferon therapy and in patients 18 years of age and older who have relapsed following alpha interferon therapy. See Rebetol prescribing information for additional information.

Chronic Hepatitis B Indicated for the treatment of chronic hepatitis B in patients 1 year of age or older with compensated liver disease. Patients who have been serum HBsAg positive for at least 6 months and have evidence of HBV replication (serum HBeAg positive) with elevated serum ALT are candidates for treatment. Studies in these patients demonstrated that Intron A therapy can produce virologic remission of this disease (loss of serum HBeAg), and normalization of serum aminotransferases. Intron A therapy resulted in the loss of serum HBsAg in some responding patients. Prior to initiation of Intron A therapy, it is recommended that a liver biopsy be performed to establish the presence of chronic hepatitis and the extent of liver damage. The physician should establish that the patient has compensated liver disease. The following patient entrance criteria for compensated liver disease were used in the clinical studies and should be considered before Intron A treatment of patients with chronic hepatitis B: - No history of hepatic encephalopathy, variceal bleeding, ascites, or other signs of clinical decompensation - Bilirubin normal - Albumin stable and within normal limits - Prothrombin Time - adults < 3 seconds prolonged, pediatrics less than or equal to 2 seconds prolonged - WBC greater than or equal to 4,000/mm³ - Platelets - adults greater than or equal to 100,000/mm³, pediatrics greater than or equal to 150,000/mm³. Patients with causes of chronic hepatitis other than chronic hepatitis B or chronic hepatitis C should not be treated with Intron A. CBC and platelet counts should be evaluated prior to initiation of Intron A therapy in order to establish baselines for monitoring potential toxicity. These tests should be repeated at treatment Weeks 1, 2, 4, 8, 12, and 16. Liver function tests, including serum ALT, albumin, and bilirubin, should be evaluated at treatment Weeks 1, 2, 4, 8, 12, and 16. HBeAg, HBsAg, and ALT should be evaluated at the end of therapy, as well as 3- and 6-months post-therapy, since patients may become virologic responders during the 6-month

period following the end of treatment. In clinical studies in adults, 39% (15/38) of responding patients lost HBeAg 1 to 6 months following the end of Intron A therapy. Of responding patients who lost HBsAg, 58% (7/12) did so 1 to 6 months post-treatment. A transient increase in ALT greater than or equal to 2 x baseline value (flare) can occur during Intron A therapy for chronic hepatitis B. In clinical trials in adults and pediatrics, this flare generally occurred 8 to 12 weeks after initiation of therapy and was more frequent in Intron A responders (adults 63%, 24/38; pediatrics 59%, 10/17) than in non-responders (adults 27%, 13/48; pediatrics 35%, 19/55). However, in adults and pediatrics, elevations in bilirubin 3 mg/dL (2 times ULN) occurred infrequently (adults 2%, 2/86; pediatrics 3%, 2/72) during therapy. When ALT flare occurs, in general, Intron A therapy should be continued unless signs and symptoms of liver failure are observed. During ALT flare, clinical symptomatology and liver function tests including ALT, prothrombin time, alkaline phosphatase, albumin, and bilirubin, should be monitored at approximately 2-week intervals.

Drug Name: Pegasys (peginterferon alfa-2a)

Chronic Hepatitis C As part of a combination regimen with other hepatitis C virus (HCV) antiviral drugs, is indicated for the treatment of adults with chronic hepatitis C (CHC) with compensated liver disease. For information about the safe and effective use of other HCV antiviral drugs to be used in combination with Pegasys, refer to their prescribing information. Pegasys in combination with ribavirin is indicated for treatment of pediatric patients 5 years of age and older with CHC and compensated liver disease. Pegasys monotherapy is only indicated for the treatment of patients with CHC with compensated liver disease if there are contraindications or significant intolerance to other HCV antiviral drugs. Limitations of use: - Pegasys alone or in combination with ribavirin without additional HCV antiviral drugs is not recommended for treatment of patients with CHC who previously failed therapy with an interferon-alfa. - Pegasys is not recommended for treatment of patients with CHC who have had solid organ transplantation.

Chronic Hepatitis B Indicated for the treatment of adult patients with HBeAg-positive and HBeAg-negative chronic hepatitis B infection who have compensated liver disease and evidence of viral replication and liver inflammation. Indicated for the treatment of HBeAg-positive CHB in non-cirrhotic pediatric patients 3 years of age and older with evidence of viral replication and elevations in serum alanine aminotransferase (ALT).

Drug Name: PegIntron (peginterferon alfa-2b)

Chronic Hepatitis C As part of a combination regimen, is indicated for the treatment of Chronic Hepatitis C (CHC) in patients with compensated liver disease. PegIntron in combination with ribavirin and an approved Hepatitis C Virus (HCV) NS3/4A protease inhibitor is indicated in adult patients with HCV genotype 1 infection (see labeling of the specific HCV NS3/4A protease inhibitor for further information). PegIntron in combination with ribavirin is indicated in patients with genotypes other than 1, pediatric patients (3-17 years of age), or in patients with genotype 1 infection where use of an HCV NS3/4A protease inhibitor is not warranted based on tolerability, contraindications or other clinical factors. PegIntron monotherapy should only be used in the treatment of CHC in patients with compensated liver disease if there are contraindications to or significant intolerance of ribavirin and is indicated for use only in previously untreated adult patients. Combination therapy provides substantially better response rates than monotherapy.

2 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C</p> <p style="text-align: center;">AND</p> <p>2 - Patients without decompensated liver disease**</p> <p style="text-align: center;">AND</p> <p>3 - For patients who have not previously been treated with interferon</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <ul style="list-style-type: none">• Contraindication or intolerance to ribavirin• Used in combination with ribavirin <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Hepatologist• Gastroenterologist• Infectious disease specialist	

<ul style="list-style-type: none"> HIV specialist certified through the American Academy of HIV Medicine 	
Notes	**Defined as Child-Pugh Class B or C

Product Name: Intron A or Pegasys	
Diagnosis	Chronic Hepatitis B
Approval Length	48 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis B infection</p> <p style="text-align: center;">AND</p> <p>2 - Patients without decompensated liver disease**</p>	
Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys or PegIntron	
Diagnosis	Chronic Hepatitis C
Approval Length	28 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C infection</p> <p style="text-align: center;">AND</p> <p>2 - Patient without decompensated liver disease**</p>	

AND

3 - One of the following:

3.1 Used in combination with one of the following:

- Sovaldi (sofosbuvir)
- Ribavirin

OR

3.2 Contraindication or intolerance to all other HCV agents (e.g., Sovaldi [sofosbuvir], ribavirin)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Notes

**Defined as Child-Pugh Class B or C

Product Name: Pegasys or PegIntron

Diagnosis | Chronic Hepatitis C

Approval Length | 20 Week(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Patient has an undetectable HCV RNA at week 24

AND

2 - Additional treatment weeks of peginterferon are required to complete treatment regimen

AND

3 - Patient has not exceeded 48 weeks of therapy with peginterferon

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name: Intron A	
Diagnosis	Condylomata acuminata
Approval Length	6 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of condylomata acuminata (genital or perianal)	

Product Name: Intron A	
Diagnosis	Diagnoses other than hepatitis and condylomata acuminata
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of hairy cell leukemia

OR

1.2 Diagnosis of AIDS-related Kaposi's sarcoma

OR

1.3 All of the following:

1.3.1 Diagnosis of metastatic renal cell carcinoma

AND

1.3.2 Used in combination with Avastin (bevacizumab)

AND

1.3.3 Prescribed by or in consultation with an oncologist

OR

1.4 Diagnosis of malignant melanoma

OR

1.5 Diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma

OR

1.6 As maintenance therapy for the treatment of multiple myeloma (non-FDA approved indication)

3 . References

1. Pegasys Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2021.
2. PegIntron Prescribing Information. Merck & Co. Whitehouse Station, NJ. August 2019.
3. Intron A Prescribing Information. Merck & Co. Whitehouse Station, NJ. November 2021.
4. Avastin Prescribing Information. Genentech, Inc. South San Francisco, CA. January 2021.
5. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed May 5, 2022.
6. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. September 2019.

Prior Authorization Guideline

Guideline Name	Alpha-1 Proteinase Inhibitors
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Aralast NP (alpha-1-proteinase inhibitor [human])
<p>Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Aralast NP increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. The effect of augmentation therapy with Alpha1-PI, including Aralast NP, on pulmonary exacerbations and on the progression of emphysema in alpha-1-antitrypsin deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and maintenance therapy with Aralast NP or Aralast are not available. Aralast NP is not indicated as therapy for lung disease patients in whom severe congenital Alpha-1-PI deficiency has not been established.</p>
Drug Name: Glassia (alpha-1-proteinase inhibitor [human])
<p>Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe hereditary deficiency of Alpha1-PI, also known as alpha1-antitrypsin (AAT) deficiency. Glassia increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with Glassia or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation and</p>

maintenance therapy of individuals with Glassia are not available. Glassia is not indicated as therapy for lung disease in patients in whom severe Alpha1-PI deficiency has not been established.

Drug Name: Prolastin-C (alpha-1-proteinase inhibitor [human]), Prolastin-C liquid (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of Alpha1-PI (alpha1-antitrypsin deficiency). Prolastin-C increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1-PI. Limitations of Use: The effect of augmentation therapy with any Alpha-1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been conclusively demonstrated in randomized, controlled clinical trials. Clinical data demonstrating the long-term effects of chronic augmentation or maintenance therapy with Prolastin-C are not available. Prolastin-C is not indicated as therapy for lung disease in patients in whom severe Alpha-1-PI deficiency has not been established.

Drug Name: Zemaira (alpha-1-proteinase inhibitor [human])

Alpha-1 proteinase inhibitor deficiency (also known as alpha-1-antitrypsin (AAT) deficiency) Indicated for chronic augmentation and maintenance therapy in adults with Alpha1-PI deficiency and clinical evidence of emphysema. Zemaira increases antigenic and functional (ANEC) serum levels and lung epithelial lining fluid levels of Alpha1-PI. Clinical data demonstrating the long-term effects of chronic augmentation therapy of individuals with Zemaira are not available. The effect of augmentation therapy with Zemaira or any Alpha1-PI product on pulmonary exacerbations and on the progression of emphysema in Alpha1-PI deficiency has not been demonstrated in randomized, controlled clinical trials. Zemaira is not indicated as therapy for lung disease patients in whom severe Alpha1-PI deficiency has not been established.

2 . Criteria

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of congenital alpha-1 antitrypsin (AAT) deficiency

AND

2 - Diagnosis of emphysema [A]

AND

3 - One of the following:

3.1 Pi*ZZ, Pi*Z(null) or Pi*(null)(null) protein phenotypes (homozygous) [6]

OR

3.2 Other rare AAT disease genotypes associated with pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter [e.g., Pi(Malton, Malton), Pi(SZ)] [B]

AND

4 - One of the following:

4.1 Circulating pre-treatment serum alpha1-antitrypsin (AAT) level less than 11 micromole per liter (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry) [B, 10]

OR

4.2 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

5 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

AND

6 - One of the following: [8, 9, 10]

6.1 The FEV1 level is less than or equal to 65% of predicted

OR

6.2 Patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment [9]

OR

6.3 Patient has a concomitant diagnosis of necrotizing panniculitis

AND

7 - Patient is NOT a current smoker [C]

Product Name: Aralast NP, Glassia, Prolastin-C, Prolastin-C liquid, or Zemaira

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Continued optimal conventional treatment for emphysema (e.g., bronchodilators)

3 . Endnotes

- A. Currently, augmentation therapy is not recommended for patients without emphysema. [3, 8] Some individuals with AAT deficiency will not go on to develop panacinar emphysema, only those with evidence of such disease should be considered for augmentation therapy.
- B. Population studies suggest a minimum plasma threshold of 11 $\mu\text{mol/L}$ (corresponding to 80 mg/dL in some assays and ~ 57 mg/dL by nephelometry), below which there is insufficient AAT to protect the lung, leading to a risk of developing emphysema. [3, 6-9]
- C. The GOLD report recommends reserving alpha-1 antitrypsin augmentation therapy for those with evidence of continued and rapid progression following smoking cessation. [8]

4 . References

1. Aralast NP Prescribing Information. Baxalta US Inc. Westlake Village, CA. December 2018.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. April 2019.
3. American Thoracic Society/European Respiratory Society Statement: Standards for diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Resp Care Med* 2003; 168:818-900.
4. ProLastin-C Prescribing Information. Grifols Therapeutics, Inc. Research Triangle Park, NC. June 2018.
5. Glassia Prescribing Information. Baxalta US Inc. Lexington, MA. December 2021.
6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. *Canadian Respiratory Journal* 2012;19(2):109-116.
7. Stoller JK. Treatment of of alpha-1 antitrypsin deficiency. UpToDate. Accessed March 12, 2019.
8. Vogelmeir C, Agusti A, et al. The global strategy for diagnosis, management and prevention of COPD (2020 Report). Global Initiative for Chronic Obstructive Lung Disease. Accessed January 21, 2020.
9. Brantly ML, Lascano JE, Shahmohammadi A. Intravenous alpha-1 antitrypsin therapy for alpha-1 antitrypsin deficiency: the current state of the evidence. *Chronic Obstr Pulm Dis.* 2019;6(1):100-114.
10. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. *Chronic Obstr Pulm Dis.* 2016; 3(3): 668-682.

Alunbrig (brigatinib)

Prior Authorization Guideline

Guideline Name	Alunbrig (brigatinib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Alunbrig (brigatinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

2 . Criteria

Product Name: Alunbrig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Alunbrig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Alunbrig Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. March 2022.
2. National Comprehensive Cancer Network (NCCN) Non-small cell lung cancer guideline. v.3.2022. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed April 28, 2022.

Ampyra (dalfampridine)

Prior Authorization Guideline

Guideline Name	Ampyra (dalfampridine)
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Ampyra (dalfampridine)
Improvement in walking in patients with multiple sclerosis Indicated as a treatment to improve walking in adult patients with multiple sclerosis (MS). This was demonstrated by an increase in walking speed.

2 . Criteria

Product Name: Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of multiple sclerosis [A]	

AND

2 - Physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - One of the following:

- Patient has an expanded disability status scale (EDSS) score less than or equal to 7
- Patient is not restricted to using a wheelchair (if EDSS is not measured)

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Both of the following (for Ampyra BRAND only):

5.1 Trial and failure, contraindication, or intolerance to generic dalfampridine

AND

5.2 Submission of documentation (chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium

Product Name: Brand Ampyra, Generic dalfampridine extended-release	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Physician confirmation that the patient's walking improved with therapy</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <ul style="list-style-type: none"> • Patient has an expanded disability status scale (EDSS) score less than or equal to 7 • Patient is not restricted to using a wheelchair (if EDSS is not measured) <p style="text-align: center;">AND</p> <p>3 - Both of the following (for Ampyra BRAND only):</p> <p>3.1 Trial and failure, contraindication, or intolerance to generic dalfampridine</p> <p style="text-align: center;">AND</p> <p>3.2 Submission of documentation (chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	

3 . Endnotes

- A. Patients with clinically definite MS of any type were included in the pivotal trials for Ampyra. [2, 3]
- B. Inclusion criteria in the Ampyra pivotal trials included patients who were able to walk (with or without an assistive device) 25 feet in 8-45 seconds and 8-60 seconds in the two studies, respectively. [2, 3]

4 . References

1. Ampyra Prescribing Information. Acorda Therapeutics, Inc. Ardsley, NY. September 2017.
2. Goodman AD, Brown TR, Krupp LB, et al. Sustained-release oral fampridine in multiple sclerosis: a randomised, double-blind, controlled trial. *Lancet* 2009;373:732-738.
3. Goodman AD, Brown TR, Cohen JA, et al. Dose comparison trial of sustained-release fampridine in multiple sclerosis. *Neurology*. 2008;1134-1141.

Amvuttra (vutrisiran)

Prior Authorization Guideline

Guideline Name	Amvuttra (vutrisiran)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Amvuttra (vutrisiran)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy	

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-3]

AND

3 - One of the following [1-4, A, B]:

- Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
- Patient has a baseline Karnofsky Performance Status score greater than or equal to 60%

AND

4 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, walking ability, quality of life) [1-3]

AND

5 - Patient has not had a liver transplant [2-3]

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Amvuttra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms from baseline (e.g., neuropathy, quality of life, gait speed, nutritional status, decrease in serum TTR level)

AND

2 - One of the following [1-4, A, B]:

- Patient continues to have a polyneuropathy disability (PND) score less than or equal to IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) greater than or equal to 5 and less than or equal to 130
- Patient continues to have a Karnofsky Performance Status score greater than or equal to 60%

3 . Endnotes

- A. The efficacy of vutrisiran was demonstrated in a phase 3, open label, randomized clinical trial (HELIOS-A) in which efficacy endpoints for vutrisiran were compared to an external placebo group from the APOLLO trial. Similar recruitment criteria were used for both HELIOS-A and APOLLO which resulted in similar baseline characteristics between the treatment groups in HELIOS-A and the placebo group in APOLLO [2-3].
- B. Baseline characteristics in HELIOS-A included 70% of patients with stage 1 disease and 30% of patients with stage 2 disease [1-2]. The European Medicines Agency lists the full indication for Amvuttra as treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy [4].

4 . References

1. Amvuttra Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. June 2022.
2. Adams D, Tournev IL, Taylor MS, et al. Efficacy and safety of vutrisiran for patients with hereditary transthyretin-mediated amyloidosis with polyneuropathy: a randomized clinical trial. *Amyloid*. 2022;1-9. Available at <https://www.tandfonline.com/doi/full/10.1080/13506129.2022.2091985>. Accessed August 4, 2022.

3. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. *BMC Neurol.* 2017;17:181.
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<https://www.ema.europa.eu/en/medicines/human/summaries-opinion/amvuttra>.
Published July 21, 2022. Accessed August 4, 2022.

Prior Authorization Guideline

Guideline Name	Anorexiant
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Guideline Note:

Effective Date:	8/1/2023
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Note:

Applicable to FEHB plans only - Carrier: SWPBSWHP; account HMOLG00011

1 . Indications

Drug Name: Contrave (naltrexone/bupropion)
Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of greater than or equal to 30 kg/m ² (obese) or greater than or equal to 27 kg/m ² (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia).
Drug Name: Qsymia (phentermine/topiramate)
Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: 1) Adult patients with an initial BMI of greater than or equal to 30 kg/m ² (obese) or greater than or equal to 27 kg/m ² (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia). 2) Pediatric patients aged 12 years and older with an initial BMI in the 95th percentile or greater standardized for age and sex.
Drug Name: Xenical (orlistat)

Obesity Management Indicated for obesity management including weight loss and weight maintenance when used in conjunction with a reduced-calorie diet. Xenical is also indicated to reduce the risk for weight regain after prior weight loss. Xenical is indicated for obese patients with an initial BMI greater than or equal to 30 kg/m² or greater than or equal to 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, dyslipidemia).

Drug Name: Saxenda (liraglutide)

Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients 12 years or older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m² or greater for adults (obese) by international cut-offs using Cole Criteria. [14] Limitations of Use: The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established.

Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of greater than or equal to 30 kg/m² (obese) or greater than or equal to 27 kg/m² (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, dyslipidemia).

Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in pediatric patients 12 years or older with body weight above 60 kg and an initial BMI corresponding to 30 kg/m² or greater for adults (obese) by international cut-offs using Cole Criteria. [14] Limitations of Use: The safety and effectiveness of Saxenda in pediatric patients with type 2 diabetes have not been established

Drug Name: Wegovy (semaglutide)

Chronic Weight Management Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of 30 kg/m² or greater (obesity), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia).

Chronic Weight Management Indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity).

Limitations of Use: Wegovy contains semaglutide and should not be coadministered with other semaglutide-containing products or with any other GLP-1 receptor agonist. The safety and effectiveness of Wegovy in combination with other products intended for weight loss, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established. Wegovy has not been studied in patients with a history of pancreatitis.

2 . Criteria

Product Name: Qsymia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Treatment is being requested for appetite suppression or weight loss [1, 2, 6]</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <p> 2.1 Submission of medical or related records of the applicable program documenting lifestyle intervention methods, within the last 12 months (e.g., weight management program, community-based/online weight-loss program, behavior modification tracking) [1, 2, 6, 7]:</p> <p style="text-align: center;">AND</p> <p> 2.2 Lifestyle intervention changes are required for 6 months prior to starting therapy and must be continued throughout therapy</p> <p style="text-align: center;">AND</p> <p>3 - One of the following: [2, 4, 15]</p> <p> 3.1 Both of the following:</p> <ul style="list-style-type: none">• Patient is 18 years of age or older• BMI greater than or equal to 30 kg/m² <p style="text-align: center;">OR</p> <p> 3.2 All of the following:</p>	

- Patient is 18 years of age or older
- BMI is greater than or equal to 27 kg/m²
- Patient has a weight-related comorbidity (e.g., hypercholesterolemia, hypertension, diabetes, sleep apnea)

OR

3.3 Both of the following:

- Patient is between 12 and 17 years of age
- Initial BMI is in the 95th percentile or greater standardized for age and sex

Product Name: Qsymia	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is greater than or equal to 12 years of age</p> <p style="text-align: center;">AND</p> <p>2 - Weight loss of greater than or equal to 5% of baseline body weight or BMI [B]</p> <p style="text-align: center;">AND</p> <p>3 - Lifestyle intervention changes are continued</p>	

Product Name: Wegovy	
Approval Length	7 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss [1, 2, 6]

AND

2 - One of the following [1, 2, 6]

2.1 Both of the following:

- Patient is 18 years of age or older
- BMI greater than or equal to 30 kg/m²

OR

2.2 All of the following:

- Patient is 18 years of age or older
- BMI is greater than or equal to 27 kg/m²
- Patient has a weight-related comorbidity (e.g., hypercholesterolemia, hypertension, diabetes, sleep apnea)

OR

2.3 Both of the following:

- Patient is between 12 and 17 years of age
- Initial BMI is in the 95th percentile or greater standardized for age and sex

AND

3 - Both of the following:

3.1 Submission of medical or related records of the applicable program documenting lifestyle intervention methods within the last 12 months (e.g., weight management program, community-based/online weight-loss program, behavior modification tracking) [1, 2, 6, 7]

AND

3.2 Lifestyle intervention changes are required for 6 months prior to starting therapy and must be continued throughout therapy

AND

4 - Medication is not being co-administered with any of the following:

- Semaglutide-containing products (e.g., Ozempic, Rybelsus)
- GLP-1 receptor agonists (e.g., Saxenda, Trulicity, Victoza)

Product Name: Wegovy	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Weight loss of greater than or equal to 5% of baseline body weight [D]	
AND	
2 - Medication is not being co-administered with any of the following:	
<ul style="list-style-type: none">• Semaglutide-containing products (e.g., Ozempic, Rybelsus)• GLP-1 receptor agonists (e.g., Saxenda, Trulicity, Victoza)	
AND	
3 - Lifestyle intervention changes are continued	

Product Name: Saxenda

Approval Length | 6 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Treatment is being requested for appetite suppression or weight loss [1, 2, 6]

AND

2 - One of the following: [1, 2, 6]

2.1 Both of the following:

- Patient is 18 years of age or older
- BMI greater than or equal to 30 kg/m²

OR

2.2 All of the following:

- Patient is 18 years of age or older
- BMI greater than or equal to 27 kg/m²
- Patient has a weight-related comorbidity (e.g., hypercholesterolemia, hypertension, diabetes, sleep apnea)

OR

2.3 All of the following:

- Patient is between 12 and 17 years of age
- Body weight above 60 kg
- Baseline BMI corresponding to 30 kg/m² for adults (obese) by international cut-offs (e.g., Cole Criteria) [8]

AND

3 - Both of the following:

3.1 Submission of medical or related records of the applicable program documenting lifestyle intervention methods within the last 12 months (e.g., weight management program, community-based/online weight-loss program, behavior modification tracking) [1, 2, 6, 7]

AND

3.2 Lifestyle intervention changes are required for 6 months prior to starting therapy and must be continued throughout therapy

AND

4 - Medication is not being co-administered with any of the following:

- Liraglutide-containing products (e.g., Victoza)
- GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Wegovy)

Product Name: Saxenda	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Both of the following:	
<ul style="list-style-type: none">• Patient is between 12 and 17 years of age• Weight loss of at least 1% from baseline body weight or BMI [14]	
OR	
1.2 Both of the following:	

- Patient is 18 years of age or older
- Weight loss of greater than or equal to 4% of baseline body weight [C]

AND

2 - Medication is not being co-administered with any of the following:

- Liraglutide-containing products (e.g., Victoza)
- GLP-1 receptor agonists (e.g., Ozempic, Rybelsus, Trulicity, Wegovy)

AND

3 - Lifestyle intervention changes are continued

Product Name: Contrave	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Treatment is being requested for appetite suppression or weight loss [1, 2, 6]</p> <p>AND</p> <p>2 - Patient is greater than or equal to 18 years of age</p> <p>AND</p> <p>3 - Both of the following:</p> <p>3.1 Submission of medical or related records of the applicable program documenting lifestyle intervention methods within the last 12 months (e.g., weight management program, community-based/online weight-loss program, behavior modification tracking) [1, 2, 6, 7]</p>	

AND

3.2 Lifestyle intervention changes are required for 6 months prior to starting therapy and must be continued throughout therapy

AND

4 - One of the following: [1, 2, 6]

4.1 BMI greater than or equal to 30 kg/m²

OR

4.2 Both of the following:

4.2.1 BMI greater than or equal to 27 kg/m²

AND

4.2.2 Patient has a weight-related comorbidity (e.g., hypercholesterolemia, hypertension, diabetes, sleep apnea)

Product Name: Xenical or Orlistat	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Treatment is being requested for appetite suppression or weight loss [1, 2, 6]	
AND	

2 - Patient is greater than or equal to 12 years of age

AND

3 - Both of the following:

3.1 Submission of medical or related records of the applicable program documenting lifestyle intervention methods within the last 12 months (e.g., weight management program, community-based/online weight-loss program, behavior modification tracking) [1, 2, 6, 7]

AND

3.2 Lifestyle intervention changes are required for 6 months prior to starting therapy and must be continued throughout therapy

AND

4 - One of the following: [1, 2, 6]

4.1 BMI greater than or equal to 30 kg/m²

OR

4.2 Both of the following:

4.2.1 BMI greater than or equal to 27 kg/m²

AND

4.2.2 Patient has a weight-related comorbidity (e.g., hypercholesterolemia, hypertension, diabetes, sleep apnea)

Product Name: Contrave, Xenical, or Orlistat

Approval Length	6 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Weight loss of greater than or equal to 5% of baseline body weight or BMI [B]</p> <p style="text-align: center;">AND</p> <p>2 - Lifestyle intervention changes are continued</p>	

3 . Endnotes

- A. A patient receiving Qsymia should have two evaluation points - after 12 weeks, followed by another 12 weeks. During the first evaluation point, patient may be dose escalated. During the second evaluation, if the patient has not yet reached goal, it is recommended to discontinue Qsymia as directed. Therefore, a 6 month authorization duration is necessary to evaluate the patient adequately before determining efficacy. [3]
- B. A patient receiving Contrave is recommended to be evaluated by week 12 at the maintenance dose after an initial titration period. [5]
- C. An adult patient receiving Saxenda should have his/her body weight evaluated at week 16 after initiating therapy. [8]
- D. If a patient's response to a weight loss medication is deemed effective (weight loss greater than or equal to 5% of body weight) and safe, it is recommended that the medication be continued. [6]
- E. A pediatric patient receiving Saxenda should have his/her BMI evaluated after maintenance dose has been achieved and patient has received 12 weeks of therapy at maintenance dose. [8]
- F. Wegovy has a 7 month approval duration for initial auth, this allows for 16 weeks of dose escalation to reach maintenance dosage and 12 additional weeks of maintenance therapy. The Endocrine Society Clinical Practice Guideline states that 3 months is a reasonable trial period for weight loss medications. [11]

4 . References

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3. Qsymia Prescribing Information. Vivus, Inc. Campbell, CA. June 2022
4. Xenical Prescribing Information. CHEPLAPHARM Arzneimittel GmbH. Greifswald, Germany. November 2020
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9. Wegovy Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. December 2022.
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11. Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*, Volume 100, Issue 2, 1 February 2015, Pages 342–362. <https://academic.oup.com/jcem/article/100/2/342/2813109>. Accessed May 17, 2022.

Prior Authorization Guideline

Guideline Name	Anti-Parkinson's Agents
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Rytary (carbidopa and levodopa) extended-release capsules
Parkinson's disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication
Drug Name: Duopa (carbidopa and levodopa) enteral suspension
Advanced Parkinson's disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson's disease.
Drug Name: Xadago (safinamide) tablets
Parkinson's disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.
Drug Name: Gocovri (amantadine) extended-release capsules
Dyskinesia in Parkinson's disease Indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

"Off" Episodes in Parkinson's Disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes.

Drug Name: Osmolex ER (amantadine) extended-release tablets

Parkinson's Disease Indicated for the treatment of Parkinson's disease.

Drug-Induced Extrapyramidal Reactions Indicated for the treatment of drug-induced extrapyramidal reactions in adult patients.

Drug Name: Neupro (rotigotine) transdermal system

Parkinson's Disease Indicated for the treatment of Parkinson's disease.

Restless Legs Syndrome (RLS) Indicated for the treatment of moderate-to-severe primary Restless Legs Syndrome.

2 . Criteria

Product Name: Rytary	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Trial and failure (of a minimum 30-day supply) of one of the following:</p> <ul style="list-style-type: none"> • Generic carbidopa-levodopa immediate release • Generic carbidopa-levodopa extended release 	

Product Name: Xadago	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p>	

1 - Trial and failure (of a minimum 30-day supply) of both of the following:

- rasagiline tablets
- selegiline capsules or tablets

Product Name: Duopa

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is levodopa-responsive [A, B]

AND

3 - Patient experiences disabling "Off" periods for a minimum of 3 hours/day [B]

AND

4 - Disabling "Off" periods occur despite therapy with both of the following: [A, C]

- Oral levodopa-carbidopa
- One drug from a different class of anti-Parkinson's disease therapy (e.g., COMT inhibitor [entacapone, tolcapone], MAO-B inhibitor [selegiline, rasagiline], dopamine agonist [pramipexole, ropinirole])

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Duopa

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Gocovri

Diagnosis | Dyskinesia in Parkinson's Disease

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing dyskinesia

AND

3 - Patient is receiving concurrent levodopa-based therapy [5, D]

AND

4 - Trial and failure or intolerance to amantadine immediate release

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri

Diagnosis	"Off" Episodes in Parkinson's Disease
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Patient is experiencing "off" episodes [E, 6]

AND

3 - Used in combination with levodopa/carbidopa therapy [1]

AND

4 - Both of the following:

4.1 Trial and failure, or intolerance to amantadine immediate release

AND

4.2 Trial and failure, contraindication or intolerance to one of the following:

- MAO-B inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri

Diagnosis	All Indications
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decreased "off" periods, decreased "on" time with troublesome dyskinesia) [D]

Product Name: Osmolex ER

Diagnosis	Parkinson's Disease
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of Parkinson's disease

AND

2 - Trial and failure, contraindication or intolerance to BOTH of the following:

2.1 amantadine immediate release

AND

2.2 ONE of the following: [9]

- carbidopa-levodopa
- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Osmolex ER	
Diagnosis	Drug-Induced Extrapyrarnidal Reactions
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient is experiencing drug-induced extrapyramidal reactions	
AND	
2 - One of the following: [10]	
2.1 Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication	
OR	

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Trial and failure or intolerance to amantadine immediate release

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease, Drug-Induced Extrapyrarnidal Reactions
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

Product Name: Neupro	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	
1 - Trial and failure, contraindication or intolerance (of a minimum 30-day supply) to one of the following generics:	

- Pramipexole immediate-release (IR)
- Pramipexole extended-release (ER)
- Ropinirole IR
- Ropinirole ER

3 . Endnotes

- A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2, 3]
- B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of "Off" time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2, 3]
- C. Most patients (89%) were taking at least one concomitant medication for Parkinson's disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2, 3]
- D. The efficacy of Gocovri was established in two Phase III randomized, double-blind, placebo-controlled trials, a 12 week and 24 week study in patients with Parkinson's disease were treated with levodopa. Both studies demonstrate statistically significant and clinically relevant reduction in dyskinesia compared to placebo. Also, both studies showed that Gocovri-treated patients experienced an increase in functional time daily (defined as ON time without troublesome dyskinesia) compared to placebo-treated patients. [6, 7]
- E. "Off" time is defined as the amount of time the Parkinson's Disease medication was not controlling motor symptoms. [6]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. *Lancet Neurol.* 2014 Feb;13(2):141-9.
3. Rytary Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2019.
4. Xadago Prescribing Information. US WorldMeds, LLC. Louisville, KY. November 2019.
5. Gocovri Prescribing Information. Adamas Pharma, LLC. Emeryville, CA. January 2021.
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8. Osmolex ER Prescribing Information. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. October 2019.
9. National Institute of Health and Clinical Excellence (NICE). Parkinson's disease in adults. NICE guideline [NG71]. July 2017. Available at: <https://www.nice.org.uk/guidance/ng71/chapter/Recommendations>. Accessed January 28, 2021.
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11. Neupro Prescribing Information. UCB, Inc. Smyrna, GA. April 2020.
12. Oertel W, Eggert K, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). *Mov Disord*. 2017;32(12):1701-1709.

Prior Authorization Guideline

Guideline Name	Antiemetics Quantity Limit Overrides
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Akynzeo (netupitant/palonosetron)
<p>Chemotherapy-induced nausea and vomiting Indicated in combination with dexamethasone in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Akynzeo is an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.</p>
Drug Name: Anzemet (dolasetron)
<p>Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy, including initial and repeat courses in adults and children 2 years and older.</p> <p>Off Label Uses: Radiotherapy-induced nausea and vomiting Used for the prevention and treatment of nausea and vomiting induced by radiation therapy. [11, 12]</p> <p>Postoperative nausea and vomiting Used orally for the prevention of postoperative nausea and vomiting. [13]</p>
Drug Name: Emend (aprepitant)

Chemotherapy-induced nausea and vomiting Indicated, in combination with other antiemetic agents, in patients 6 months of age and older for oral suspension, or 12 years of age and older for the capsules, for the prevention of: (1) acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin; (2) nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

Postoperative Nausea and Vomiting - capsules only Indicated in adults for the prevention of postoperative nausea and vomiting. Limitations of Use: (1) Emend has not been studied for the treatment of established nausea and vomiting; (2) Chronic continuous administration of Emend is not recommended because it has not been studied, and because the drug interaction profile may change during chronic continuous use.

Drug Name: Granisetron

Chemotherapy-induced nausea vomiting Indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy, including high-dose cisplatin.

Radiation-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiation, including total body irradiation and fractionated abdominal radiation.

Off Label Uses: Postoperative nausea and vomiting Used for the prevention of postoperative nausea and vomiting. [14, 15]

Drug Name: Marinol (dronabinol)

Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

Anorexia in patients with AIDS Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS.

Drug Name: Sancuso (granisetron transdermal system)

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy regimens of up to 5 consecutive days duration.

Drug Name: Sustol (granisetron injection)

Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated

with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

Drug Name: Varubi (rolapitant)

Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

Drug Name: Zofran (ondansetron), Zuplenz (ondansetron oral soluble film)

Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m². Also indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.

Radiotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.

Postoperative nausea and vomiting Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, Zofran Oral Solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low.

Off Label Uses: Hyperemesis gravidarum Used in the management of hyperemesis gravidarum. [10, 16]

2 . Criteria

Product Name: Akynzeo, Anzemet, Generic dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, Varubi, Brand Zofran oral solution, or Zuplenz

Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving moderately to highly emetogenic chemotherapy

AND

3 - Provider attests that a higher quantity is needed due to the number of chemotherapy sessions

Product Name: Anzemet, granisetron, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, or Zuplenz

Diagnosis	Radiotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of radiotherapy-induced nausea and vomiting

AND

2 - Patient is receiving radiotherapy consisting of total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen

AND

3 - Provider attests that a higher quantity is needed due to the number of radiation sessions

Product Name: Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Brand Zofran oral solution, or Zuplenz

Diagnosis	Hyperemesis gravidarum
Approval Length	6 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]</p> <p style="text-align: center;">AND</p> <p>2 - History of failure, contraindication, or intolerance to at least one of the following: [A]</p> <ul style="list-style-type: none"> • doxylamine • metoclopramide (Reglan) • prochlorperazine (Compazine) • promethazine (Phenergan) • pyridoxine (Vitamin B6) <p style="text-align: center;">AND</p> <p>3 - Patient has had at least a partial response to therapy at a dose within the quantity limit</p>	

3 . Background

Benefit/Coverage/Program Information
<p>Quantity Limit</p> <p>These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.</p>

4 . Endnotes

- A. Treatment of nausea and vomiting of pregnancy with vitamin B6 or vitamin B6 plus doxylamine is safe and effective and should be considered first-line pharmacotherapy (Level A Evidence). Treatment of nausea and vomiting of pregnancy with ginger has shown beneficial effects and can be considered as a nonpharmacologic option (Level B Evidence). Several types of dopamine antagonists can be used for the treatment of nausea and vomiting of pregnancy such as promethazine, prochlorperazine, and metoclopramide. Antihistamines (such as dimenhydrinate and diphenhydramine) have been shown to be effective in controlling nausea and vomiting symptoms of pregnancy and are frequently used. Evidence is limited on the safety or efficacy of the 5-HT₃ inhibitors (e.g. ondansetron) for nausea and vomiting of pregnancy. The ACOG recommends discussing the available data with patients as well as weighing the risks and benefits in women less than 10 weeks of gestation. Because of their limited data, they should not be advocated for first-line use until agents with established safety and efficacy have been tried and have failed. Treatment of severe nausea and vomiting of pregnancy or hyperemesis gravidarum with methylprednisolone may be efficacious in refractory cases; however, the risk profile of methylprednisolone suggests it should be a treatment of last resort (Level B Evidence). [16]

5 . References

1. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. October 2020.
2. Anzemet prescribing information. Validus Pharmaceuticals LLC. Parsippany, NJ. September 2021.
3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. February 2021.
4. Granisetron prescribing information. Ascend Laboratories. Montvale, NJ. March 2011.
5. Marinol prescribing information. AbbVie Inc. North Chicago, IL. October 2019.
6. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminster, NJ. June 2020.
7. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
8. Zofran prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2020.
9. Zuplenz prescribing information. Fortovia Therapeutics, Inc. Raleigh, NC. May 2020.
10. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: <http://www.thomsonhc.com/>. Accessed September 9, 2021.
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13. AHFS Drug Information website. Available at: <https://online.lexi.com/lco/action/doc/retrieve/docid/250/413041>. Accessed September 9, 2021.
14. Fujii Y, Tanaka H, Kawasaki T. Preoperative oral granisetron for the prevention of postoperative nausea and vomiting after breast surgery. *Eur J Surg*. 2001 Mar;167(3):184-7.

15. Fujii Y, Tanaka H, Kawasaki T. Prophylaxis with oral granisetron for the prevention of nausea and vomiting after laparoscopic cholecystectomy: a prospective randomized study. *Arch Surg.* 2001 Jan;136(1):101-4.
16. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2018; 103(1):15-30.
17. Sustol prescribing information. Heron Therapeutics. San Diego, CA. May 2017.

Prior Authorization Guideline

Guideline Name	Antimalarial Agents
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Qalaaquin (quinine sulfate)
<p>Malaria Indicated only for treatment of uncomplicated Plasmodium falciparum malaria. Quinine sulfate has been shown to be effective in geographical regions where resistance to chloroquine has been documented. Oral capsules are not approved for patients with severe or complicated P. falciparum malaria. Oral capsules are not approved for prevention of malaria. Oral capsules are not approved for the treatment or prevention of nocturnal leg cramps.</p>

2 . Criteria

Product Name: Brand Qalaaquin, Generic quinine sulfate	
Diagnosis	Nocturnal Leg Cramps*
Guideline Type	Prior Authorization
Approval Criteria	

1 - Requests for coverage when used solely for the treatment or prevention of nocturnal leg cramps are not authorized and will not be approved [1, C]

Notes

*Nocturnal leg cramp is an off-label use.

Product Name: Brand Qualaquin, Generic quinine sulfate

Diagnosis

Malaria

Approval Length

7 days [1]

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of uncomplicated malaria

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Treatment in areas of chloroquine-sensitive malaria [2-4, A]*

AND

2.1.2 Trial and failure, contraindication or intolerance to one of the following:

- chloroquine
- hydroxychloroquine

OR

2.2 Treatment in areas of chloroquine-resistant malaria [2-4, B]*

Notes

*Call the Malaria Hotline (770-488-7788) for additional information if needed.

3 . Endnotes

- A. Areas of chloroquine-sensitive malaria include: Central America west of the Panama Canal, Haiti, the Dominican Republic, and most of the Middle East. [2-4]
- B. Areas of chloroquine-resistant malaria include: Southeast Asia, and all malarious regions except those specified as chloroquine-sensitive listed in Endnote A. [2-4]
- C. Quinine is not approved for and should not be used for the prophylaxis or treatment of nocturnal leg cramps. Quinine may cause unpredictable serious and life-threatening hematologic reactions including thrombocytopenia and hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura (HUS/TTP) in addition to hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias including torsades de pointes, and other serious adverse events requiring medical intervention and hospitalization. Chronic renal impairment associated with the development of TTP, and fatalities have also been reported. The risk associated with the use of quinine in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating and/or preventing this benign, self-limiting condition. [1]

4 . References

1. Qulaquin Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2019.
2. Center for Disease Control Traveler's Health - Yellow Book 2020 edition. Chapter 4: Infectious diseases related to travel - malaria. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria>. Accessed May 112, 2021.
3. Center for Disease Control. Guideline for treatment of malaria in the United States. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Accessed May 12, 2021.
4. Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. A systematic review. JAMA. 2007;297(20):2264-77.

Prior Authorization Guideline

Guideline Name	Apomorphine Products
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Apokyn (apomorphine injection)
Parkinson’s Disease Indicated for the acute, intermittent treatment of hypomobility, “off” episodes (“end-of-dose wearing off” and unpredictable “on/off” episodes) in patients with advanced Parkinson’s disease. Apokyn has been studied as an adjunct to other medications.

2 . Criteria

Product Name: Brand Apokyn, Generic Apomorphine Hydrochloride Inj	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Parkinson’s disease	

AND

2 - Patient is experiencing intermittent OFF episodes

AND

3 - One of the following:

3.1 Patient is receiving drug in combination with carbidopa/levodopa at a maximally tolerated dose

OR

3.2 Patient has a contraindication or intolerance to carbidopa/levodopa

AND

4 - Trial and failure (of a minimum 30 day supply), contraindication or intolerance to two of the following: [A]

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Both of the following:

5.1 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to generic apomorphine (Applies to Brand Apokyn only)

AND

5.2 One of the following:

5.2.1 Trial and failure (of a minimum 30 day supply), contraindication or intolerance to Inbrija (levodopa) inhalation powder

OR

5.2.2 For continuation of prior therapy

AND

6 - Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron)

AND

7 - Prescribed by or in consultation with a neurologist

Product Name: Brand Apokyn, Generic Apomorphine Hydrochloride Inj

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Apokyn prescribing information. US WorldMeds, LLC. Louisville, KY. June 2022.
2. Obering CD, Chen JJ, Swope DM. Update on apomorphine for the rapid treatment of hypomobility ("off") episodes in Parkinson's disease. Pharmacotherapy. 2006;26(6):840-852.
3. Per clinical consult with neurologist, March 27, 2019.

Prior Authorization Guideline

Guideline Name	Arcalyst (rilonacept)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Arcalyst (rilonacept) injection
Cryopyrin-Associated Periodic Syndromes (CAPS) Indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS) in adults and pediatric patients 12 years and older.
Deficiency of Interleukin-1 Receptor Antagonist (DIRA) Indicated for the maintenance of remission of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in adults and pediatric patients weighing at least 10 kg.
Recurrent Pericarditis Indicated for the treatment of recurrent pericarditis and reduction in risk of recurrence in adults and pediatric patients 12 years and older.

2 . Criteria

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS) [A]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist</p> <p style="text-align: center;">AND</p> <p>3 - The medication will not be used in combination with another biologic agent</p>	

Product Name: Arcalyst	
Diagnosis	Cryopyrin-Associated Periodic Syndromes (CAPS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidenced by one of the following:</p> <ul style="list-style-type: none"> • Improvement in rash, fever, joint pain, headache, or conjunctivitis • Decreased number of disease flare days • Normalization of inflammatory markers (C-reactive protein [CRP], erythrocyte sedimentation rate [ESR], serum amyloid A [SAA]) • Corticosteroid dose reduction • Improvement in MD global score or active joint count 	

Product Name: Arcalyst	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)</p> <p style="text-align: center;">AND</p> <p>2 - Patient weighs at least 10 kg</p> <p style="text-align: center;">AND</p> <p>3 - Patient is currently in remission (e.g., no fever, skin rash, and bone pain; no radiological evidence of active bone lesions; C-reactive protein [CRP] less than 5 mg/L)</p>	

Product Name: Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of recurrent pericarditis as evidenced by at least 2 episodes that occur a minimum of 4 to 6 weeks apart [1, 4-5]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a cardiologist</p>	

AND

3 - Trial and failure, contraindication, or intolerance to at least one of the following [4-5]:

- nonsteroidal anti-inflammatory drugs (e.g., ibuprofen, naproxen)
- colchicine
- corticosteroids (e.g., prednisone)

Product Name: Arcalyst	
Diagnosis	Recurrent Pericarditis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Definitions

Definition	Description
CIAS1 gene:	Also known as cold-induced auto-inflammatory syndrome 1, is a gene responsible for the regulation of IL-1 production. Mutation(s) in this gene leads to CAPS. [2]
Chronic Infantile Neurologic Cutaneous and Articular Syndrome:	Also known as neonatal-Onset Multisystem Inflammation, is the most severe form of the CAPS. It is characterized by nearly continuous symptoms of inflammation presenting first during the neonatal period or early infancy with migratory and nonpruritic urticaria-like rash and fever. Other features of this disease include chronic aseptic meningitis, sensorineural hearing loss and ocular changes (conjunctivitis, optic nerve atrophy), and disabling arthropathy caused by overgrowth of the patella and epiphyses of

	the long bones. Approximately 20% of patients with this disease die before reaching adulthood. [2, 3]
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [2, 3]
Familial Cold Autoinflammatory Syndrome:	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [2, 3]
Muckle-Wells Syndrome:	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [2, 3]

4 . Endnotes

- A. CAPS refer to rare genetic syndromes generally caused by mutations in the NLRP-3 [Nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]). CAPS disorders are inherited in an autosomal dominant pattern with male and female offspring equally affected. Features common to all disorders include fever, urticaria-like rash, arthralgia, myalgia, fatigue, and conjunctivitis. In most cases, inflammation in CAPS is associated with mutations in the NLRP-3 gene which encodes the protein cryopyrin, an important component of the inflammasome. Mutations in NLRP-3 result in an overactive inflammasome resulting in excessive release of activated IL-1β that drives inflammation. [1]

5 . References

1. Arcalyst Prescribing Information. Regeneron Pharmaceuticals. Zug, Switzerland. March 2021.

2. Aksentijevich I, Putnam CD, Remmers EF, et al. The clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North American Patients and a new cryopyrin model. *Arthritis Rheum.* 2007; 56(4):1273-1285.
3. McDermott M, Aksentijevich I. The auto-inflammatory syndromes. *Curr Opin Allergy Clin Immunol.* 2002; 2:511-516.
4. Chiabrando JG, Bonaventura A, Vecchie A, et al. Management of acute and recurrent pericarditis. *J Am Coll Cardiol.* 2020;75(1):76–92.
5. Klein AL, Imazio M, Cremer P, et al. Phase 3 trial of interleukin-1 trap rilonacept in recurrent pericarditis. *N Engl J Med* 2021;384:31-41.

Prior Authorization Guideline

Guideline Name	Atopic Dermatitis Topical Agents
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Eucrisa (crisaborole) ointment
Atopic Dermatitis Indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 3 months of age and older.

2 . Criteria

Product Name: Eucrisa	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria	
1 - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to one	

prescription strength topical corticosteroid (see Table 1 in Background section), unless the affected area is sensitive (i.e., face, axillae, groin). [1]

OR

2 - Trial and failure (of a minimum 30 day supply) or intolerance to one generic topical calcineurin inhibitor (e.g., tacrolimus ointment), unless the patient is not a candidate for therapy (e.g., immunocompromised) [4]

3 . Background

Clinical Practice Guidelines

Table 1. Topical Corticosteroids [3]

Brand Name	Generic Name
Hytone [®] , Cortaid [®]	Hydrocortisone acetate
Aclovate [®]	Alclometasone
DesOwen [®] , Tridelison [®]	Desonide
Kenalog [®]	Triamcinolone acetonide
Synalar [®]	Fluocinolone acetonide
Valisone [®]	Betamethasone valerate
Cordran [®]	Flurandrenolide
Cutivate [®]	Fluticasone
Diprosone [®]	Betamethasone dipropionate
Elocon [®]	Mometasone
Locoid [®]	Hydrocortisone butyrate
Cyclocort [®]	Amcinonide
Diprolene [®]	Augmented betamethasone dipropionate
Halog [®]	Halcinonide
Lidex [®]	Fluocinonide
Topicort [®]	Desoximetasone
ApexiConE [®]	Diflorasone diacetate
Temovate [®]	Clobetasol propionate
Ultravate [®]	Halobetasol propionate
Vanos [®]	Fluocinonide

4 . References

1. Ference JD, Last AR. Choosing Topical Corticosteroids. Am Fam Physician. 2009 Jan 15;79 (2):135-40.
2. Eucrisa Prescribing Information. Pfizer, Inc. New York, NY. April 2020.
3. Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: <http://online.lexi.com/>. Accessed January 4, 2021.
4. Protopic Prescribing Information. Leo Pharma Inc. Madison, NJ. February 2019.

Prior Authorization Guideline

Guideline Name	Atypical Antipsychotics
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Nuplazid*	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of Parkinson's disease</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient has at least one of the following:</p>	

- Hallucinations
- Delusions

OR

1.2 For continuation of prior therapy

Notes

*Product may be excluded depending on the plan.

2 . References

1. Fanapt Prescribing Information. Vanda Pharmaceuticals, Inc.; Washington, D.C. February 2017.
2. Vraylar Prescribing Information. Allergan USA, Inc.; Irvine, CA. November 2017.
3. Nuplazid Prescribing Information. Acadia Pharmaceuticals Inc.; San Diego, CA. June 2018.

Aubagio (teriflunomide), Tecfidera (dimethyl fumarate), Gilenya/Tascenso ODT (fingolimod)

Prior Authorization Guideline

Guideline Name	Aubagio (teriflunomide), Tecfidera (dimethyl fumarate), Gilenya/Tascenso ODT (fingolimod)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Aubagio (teriflunomide)
Relapsing forms of multiple sclerosis (MS) Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Tecfidera (dimethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Gilenya (fingolimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.
Drug Name: Tascenso ODT (fingolimod)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older.

2 . Criteria

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [3]</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <p style="padding-left: 20px;">2.1 Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to generic dimethyl fumarate</p> <p style="text-align: center;">AND</p> <p style="padding-left: 20px;">2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) after a trial of at least 4 weeks documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure</p>	

after a trial of at least 4 weeks, or intolerance to at least one of the following disease-modifying therapies for MS: [A, 5]

- Bafiertam (monomethyl fumarate)
- Vumerity (diroximel fumarate)

AND

4 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic dimethyl fumarate

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [4]

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Brand Tecfidera, generic dimethyl fumarate

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - Both of the following (applies to BRAND Tecfidera only):

4.1 Trial and failure of at least a 4-week trial or intolerance to generic dimethyl fumarate

AND

4.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) after a trial of at least 4 weeks documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Aubagio	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to generic teriflunomide</p> <p style="text-align: center;">AND</p> <p>3 - Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) <p style="text-align: center;">AND</p> <p>4 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Brand Gilenya	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to generic fingolimod (only applicable to available strengths)</p> <p style="text-align: center;">AND</p> <p>3 - Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) <p style="text-align: center;">AND</p> <p>4 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Tascenso ODT	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Patient is 10 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient is 18 years of age or older

AND

3.1.2 One of the following:

3.1.2.1 For continuation of therapy

OR

3.1.2.2 Both of the following:

3.1.2.2.1 Failure after a trial of at least 4 weeks, contraindication, or intolerance to generic fingolimod (supported by submission of medical records)

AND

3.1.2.2.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least TWO of the following:

- Teriflunomide

- Avonex (interferon beta-1a)
- Copaxone/Glatopa (glatiramer acetate)
- Extavia (interferon beta-1b)
- Kesimpta (ofatumumab)
- Plegridy (peginterferon beta-1a)
- Dimethyl fumarate
- Zeposia (ozanimod)

OR

3.2 Both of the following:

- Patient is younger than 18 years of age
- Failure after a trial of at least 4 weeks or intolerance to fingolimod (supported by submission of medical records)

AND

4 - Not used in combination with another disease-modifying therapy for MS [B 6, 7]

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic fingolimod, Generic teriflunomide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [4]</p> <p>AND</p>	

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya, Brand Aubagio, Tascenso ODT, generic fingolimod, generic teriflunomide

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - One of the following:

4.1 Both of the following: (applies to BRAND Aubagio only)

4.1.1 Trial and failure of at least a 4-week trial or intolerance to teriflunomide

AND

4.1.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

OR

4.2 Both of the following: (applies to BRAND Tascenso ODT and Gilenya [only applicable to available strengths])

4.2.1 Trial and failure of at least a 4-week trial or intolerance to generic fingolimod

AND

4.2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . Endnotes

- A. Although the trial results of Bafiertam and Vumerity were based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile as Tecfidera since they were approved via the FDA 505(b)(2) pathway. [5]
- B. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [6, 7]

4 . References

1. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurology* 2018;90:777-788.
2. National Multiple Sclerosis Society. Types of MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Types-of-MS>. Accessed March 29, 2019.
3. Tecfidera Prescribing Information. Biogen Idec Inc. Cambridge, MA. January 2021.
4. Dimethyl Fumarate Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. May 2020.
5. Per clinical consultation with MS specialist, July 22, 2020.
6. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. *Mayo Clinic Proceedings*, 89(2), 225-240.
7. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. *The Lancet Neurology*, 10(8), 691-701.
8. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. November 2020.
9. Gilenya Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. December 2019.
10. Tasenso ODT Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, United Kingdom. December 2022.

Austedo (deutetrabenazine)

Prior Authorization Guideline

Guideline Name	Austedo (deutetrabenazine)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Austedo (deutetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease in adults.
Tardive Dyskinesia Indicated for tardive dyskinesia in adults.
Drug Name: Austedo XR (deutetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease in adults.
Tardive Dyskinesia Indicated for tardive dyskinesia in adults.

2 . Criteria

Product Name: Austedo, Austedo XR	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chorea associated with Huntington's disease [1, 3, 4]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a neurologist [1, B]</p>	

Product Name: Austedo, Austedo XR	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy [1]</p>	

Product Name: Austedo, Austedo XR	
Diagnosis	Tardive Dyskinesia
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of tardive dyskinesia [1, C]</p>	

AND

2 - Disease severity is one of the following:

- Moderate
- Severe

AND

3 - One of the following [7, D]:

3.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

3.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Austedo, Austedo XR	
Diagnosis	Tardive Dyskinesia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates positive clinical response to therapy [1]

3 . Endnotes

- A. Authorization period is based on the pivotal study duration of 12 weeks. [1, 5, 6]
- B. Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). [1, 2]
- C. Patients were included in the pivotal randomized, double-blind, placebo-controlled trial of Austedo if they had moderate to severe tardive dyskinesia as determined by clinical observation (qualitative assessment). [6]
- D. Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [8]

4 . References

1. Austedo Prescribing Information. Teva Pharmaceuticals USA, Inc. Parsippany, PA. May 2022.
2. Armstrong MJ, Miyasaki JM. Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2012 August.
3. Claassen DO, Carroll B, De Boer LM, et al. Indirect tolerability comparison of deutetrabenazine and tetrabenazine for Huntington disease. *J Clin Mov Disord*. 2017. 4:3.
4. Geschwind MD, Paras N. Deutetrabenazine for treatment of chorea in Huntington disease. *JAMA*. 2016;316(1):33-34.
5. Huntington Study Group. Effect of deutetrabenazine on chorea among patients with Huntington disease. *JAMA*. 2016;316(1):40-50.
6. Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: The ARM-TD study. *Neurology*. 2017;88(21):2003-10.
7. Waln O, Jankovic J: An update on tardive dyskinesia: from phenomenology treatment. *Tremor Other Hyperkinet Mov (N Y)* 2013; 3: tre-03-161-4138-1.
8. Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.
9. Austedo XR Prescribing Information. Teva Neuroscience, Inc. Parsippany, NJ. February 2023.

Prior Authorization Guideline

Guideline Name	Ayvakit (avapritinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Ayvakit (avapritinib)
<p>Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations.</p> <p>Advanced Systemic Mastocytosis (AdvSM) Indicated for the treatment of adult patients with advanced systemic mastocytosis (AdvSM). AdvSM includes patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL). Limitations of Use: Ayvakit is not recommended for the treatment of patients with AdvSM with platelet counts of less than $50 \times 10^9/L$.</p> <p>Indolent Systemic Mastocytosis (ISM) Indicated for the treatment of adult patients with indolent systemic mastocytosis (ISM). Limitations of Use: Ayvakit is not recommended for the treatment of patients with ISM with platelet counts of less than $50 \times 10^9/L$.</p>

2 . Criteria

Product Name: Ayvakit	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> • Unresectable • Metastatic <p style="text-align: center;">AND</p> <p>3 - Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations</p>	

Product Name: Ayvakit	
Diagnosis	Advanced Systemic Mastocytosis (AdvSM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of advanced systemic mastocytosis (AdvSM)</p> <p style="text-align: center;">AND</p>	

2 - Patient has one of the following:

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with an associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

AND

3 - Platelet count is greater than $50 \times 10^9/L$

Product Name: Ayvakit

Diagnosis	Gastrointestinal Stromal Tumor (GIST), Advanced Systemic Mastocytosis (AdvSM)
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Ayvakit 25 mg

Diagnosis	Indolent Systemic Mastocytosis (ISM)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of indolent systemic mastocytosis (ISM)

AND

2 - Platelet count is greater than 50 x 10 ⁹ /L	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Ayvakit 25 mg	
Diagnosis	Indolent Systemic Mastocytosis (ISM)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	
Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Ayvakit Prescribing Information. Blueprint Medicines Corporation. Cambridge, MA. May 2023.

Prior Authorization Guideline

Guideline Name	Azole Antifungals - PA, NF
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Sporanox (itraconazole) capsules
<p>Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary</p> <p>Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis</p> <p>Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy</p> <p>Onychomycosis of the toenail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (Tinea unguium)</p> <p>Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)</p>
Drug Name: Sporanox Pulse Pak (itraconazole)

Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (*Tinea unguium*)

Drug Name: Sporanox (itraconazole) oral solution

Oropharyngeal and esophageal candidiasis Indicated for the treatment of oropharyngeal and esophageal candidiasis.

Drug Name: Tolsura (itraconazole) capsules

Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.

Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis.

Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.

Drug Name: Noxafil (posaconazole) tablets

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in adult and pediatric patients 2 years of age and older who weigh greater than 40 kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in adult and pediatric patients 2 years of age and older who weigh greater than 40kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Treatment of Invasive Aspergillosis Indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil (posaconazole) oral suspension

Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in patients 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with

hematologic malignancies with prolonged neutropenia from chemotherapy.

Oropharyngeal candidiasis Indicated for treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole in adults and pediatric patients 13 years of age and older.

Drug Name: Noxafil PowderMix (posaconazole) for delayed-release oral suspension

Prophylaxis of Invasive Aspergillus and Candida Infections Indicated for the prophylaxis of invasive Aspergillus and Candida infections in pediatric patients 2 years of age and older who weigh 40 kg or less, who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Drug Name: Vfend (voriconazole) oral suspension, Vfend (voriconazole) tablets

Invasive Aspergillosis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of invasive aspergillosis (IA). In clinical trials, the majority of isolates recovered were Aspergillus fumigatus. There was a small number of cases of culture-proven disease due to species of Aspergillus other than A. fumigatus.

Candidemia in Non-neutropenic Patients and Other Deep Tissue Candida Infections Indicated in adults and pediatric patients (2 years of age and older) for the treatment of candidemia in non-neutropenic patients and the following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and wounds.

Esophageal Candidiasis Indicated in adults and pediatric patients (2 years of age and older) for the treatment of esophageal candidiasis (EC) in adults and pediatric patients 2 years of age and older.

Scedosporiosis and Fusariosis Indicated for the treatment of serious fungal infections caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) and Fusarium spp. including Fusarium solani, in adults and pediatric patients (2 years of age and older) intolerant of, or refractory to, other therapy.

Drug Name: Cresemba (isavuconazonium sulfate) capsules

Invasive Aspergillosis Indicated for patients 18 years of age and older for the treatment of invasive aspergillosis.

Invasive Mucormycosis Indicated for patients 18 years of age and older for the treatment of invasive mucormycosis.

2 . Criteria

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Systemic and topical fungal infections
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis)</p> <p style="text-align: center;">OR</p> <p>2 - All of the following:</p> <p>2.1 One of the following diagnoses:</p> <ul style="list-style-type: none"> • Tinea corporis (ring worm) • Tinea cruris (jock itch) • Tinea pedis (athlete's foot) • Tinea capitis (scalp ringworm) • Pityriasis versicolor <p style="text-align: center;">AND</p> <p>2.2 One of the following:</p> <p>2.2.1 The tinea infection is resistant to topical antifungal treatment</p> <p style="text-align: center;">OR</p> <p>2.2.2 Trial and failure, contraindication, or intolerance to oral terbinafine [3]</p>	

Product Name: Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak	
Diagnosis	Fingernail Onychomycosis
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Fungal culture
- Nail biopsy

AND

2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Toenail Onychomycosis
Approval Length	3 Month [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:</p> <ul style="list-style-type: none">• Positive potassium hydroxide (KOH) preparation• Fungal culture• Nail biopsy <p>AND</p> <p>2 - The patient's condition is causing debility or a disruption in their activities of daily living</p>	

(e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]

AND

3 - Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine

Product Name: Brand Sporanox oral solution or generic itraconazole oral solution	
Diagnosis	Candidiasis (esophageal or oropharyngeal)
Approval Length	1 month [E, F]
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Diagnosis of esophageal candidiasis	
OR	
1.2 Diagnosis of oropharyngeal candidiasis (OPC)	
AND	
2 - One of the following:	
<ul style="list-style-type: none">• Trial and failure, contraindication, or intolerance to fluconazole• Susceptibility results demonstrate resistance to fluconazole	

Product Name: Tolsura	
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following fungal infections:

- Blastomycosis
- Histoplasmosis
- Aspergillosis

AND

2 - Trial and failure or intolerance to generic itraconazole capsules

Product Name: Noxafil oral suspension	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of oropharyngeal candidiasis (OPC)</p> <p>AND</p> <p>2 - Patient is 13 years of age and older</p> <p>AND</p> <p>3 - One of the following:</p> <ul style="list-style-type: none">• Trial and failure, contraindication, or intolerance to fluconazole• Susceptibility results demonstrate resistance to fluconazole	

Product Name: Noxafil oral suspension	
Diagnosis	Oropharyngeal Candidiasis
Approval Length	1 Month [E]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of oropharyngeal candidiasis (OPC)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 13 years of age and older</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <ul style="list-style-type: none"> • Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to fluconazole • Submission of medical records (e.g., chart notes) documenting susceptibility results demonstrate resistance to fluconazole 	

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used as prophylaxis of invasive fungal infections caused by one of the following:</p> <ul style="list-style-type: none"> • Aspergillus • Candida 	

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40 kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - One of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)
- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix

Diagnosis

Prophylaxis of systemic fungal infections

Approval Length	6 Months [B-D]
Guideline Type	Non Formulary

Approval Criteria

1 - Used as prophylaxis of invasive fungal infections caused by one of the following:

- Aspergillus
- Candida

AND

2 - One of the following:

2.1 For Noxafil (posaconazole) oral tablet, both of the following:

- Patient is 2 years of age and older
- Patient weighs greater than 40kg

OR

2.2 For Noxafil oral suspension, patient is 13 years of age and older

OR

2.3 For Noxafil PowderMix, both of the following:

- Patient is 2 years of age and older
- Patient weighs 40 kg or less

AND

3 - One of the following:

3.1 Patient is at high risk of infections due to severe immunosuppression from one of the following conditions:

- Hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD)

- Hematologic malignancies with prolonged neutropenia from chemotherapy

OR

3.2 Patient has a prior fungal infection requiring secondary prophylaxis [15, G]

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of invasive aspergillosis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 13 years of age and older</p>	

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of invasive aspergillosis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 13 years of age and older</p>	

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Invasive Aspergillosis
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of invasive aspergillosis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age and older</p>	

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Serious Fungal Infections
Approval Length	6 Months [16, B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of serious fungal infections (e.g., Scedosporium apiospermum, Fusarium species including Fusarium solani)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age and older</p> <p style="text-align: center;">AND</p> <p>3 - Patient is intolerant of, or refractory to, other therapy (e.g., amphotericin B)</p>	

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Candidemia in non-neutropenic patients and other deep tissue Candida infections
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Candidemia • Deep tissue Candida infection (e.g., disseminated in skin, infection in abdomen, kidney, bladder wall, and wounds) <p style="text-align: center;">AND</p> <p>2 - Patient is non-neutropenic</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 2 years of age and older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <ul style="list-style-type: none"> • Trial and failure, contraindication or intolerance to fluconazole [I] • Susceptibility results demonstrate resistance to fluconazole [K] 	

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Esophageal Candidiasis
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of esophageal candidiasis

AND

2 - Patient is 2 years of age and older

AND

3 - One of the following:

- Trial and failure, contraindication, or intolerance to fluconazole
- Susceptibility results demonstrate resistance to fluconazole

Product Name: Cresemba oral capsule	
Approval Length	6 Months [17, B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following fungal infections: [17]</p> <ul style="list-style-type: none">• Invasive aspergillosis• Invasive mucormycosis <p>AND</p> <p>2 - Patient is 18 years of age and older</p>	

3 . Endnotes

- A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]
- B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]
- C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis.” [11]
- D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]
- E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. For fluconazole-refractory esophageal candidiasis, itraconazole or voriconazole for 14 to 21 days is recommended. [3, 5]
- F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]
- G. NCCN recommends secondary prophylaxis with an appropriate antifungal agent in patients with prior chronic disseminated candidiasis or with invasive filamentous fungal infection during subsequent cycles of chemotherapy or HSCT. In patients with invasive aspergillosis before HSCT, antifungal therapy for more than a month and resolution of radiologic abnormalities correlate with a lower likelihood of post-transplant recurrence of infection. Secondary prophylaxis with a mold-active agent is advised for the entire period of immunosuppression. Secondary prophylaxis is generally administered for the duration of immunosuppression. Per recommendation from an infectious disease specialist, posaconazole is used for secondary prophylaxis of prior fungal infections. [15]
- H. Voriconazole prescribing information states that for candidemia in non-neutropenic patients and other deep tissue Candida infections, patients should be treated for at least 14 days following resolution of symptoms or following last positive culture, whichever is long. For esophageal candidiasis, patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms. [16]
- I. According to the 2016 IDSA guideline for candidemia in nonneutropenic patients, fluconazole, intravenous or oral, is an acceptable alternative to an echinocandin (e.g., caspofungin, micafungin, anidulafungin) in patients who are not critically ill and who are considered unlikely to have fluconazole-resistant Candida species. Voriconazole is effective for candidemia, however, offers little advantage over fluconazole as the initial therapy. [5]
- J. According to the 2016 IDSA guideline for the treatment of esophageal candidiasis, oral fluconazole 200-400 mg for 14 to 21 days is strongly recommended (high-quality evidence). Intravenous fluconazole may be used in patients who cannot tolerate oral

therapy. For fluconazole-refractory disease, voriconazole either intravenous or oral is recommended. [5]

- K. Of the *Candida* species, *C. krusei* and *C. glabrata* are the two species with higher likelihood of fluconazole-resistance for serious candida infections due to widespread azole treatment. In these cases, voriconazole may be used as oral therapy in patients with infections due to *C. krusei* or fluconazole-resistant, voriconazole-susceptible *C. glabrata* infections. [5]

4 . References

1. Sporanox Capsules Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. December 2019.
2. Sporanox Oral Solution Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. April 2019.
3. Ely J, Rosenfeld S, Stone M. Diagnosis and Management of Tinea Infections. Aafp.org. <https://www.aafp.org/afp/2014/1115/p702.html>. Published 2014. Accessed October 28, 2019
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5. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;62:e1-50.
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9. Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. *Br J Dermatol*. 2003;148:402-410.
10. Chapman SW, Dismukes WE, Proia LA, et al. Clinical practice guidelines for the management of blastomycosis: 2008 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2008;46:1801-1812.
11. Wheat LJ, Freifeld AG, Kleiman MB, et al. Clinical practice guidelines for the management of patients with histoplasmosis: 2007 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2007;45:807-825.
12. Patterson TF, Thompson GR, Denning DW, et al. Practice guidelines for the diagnosis and management of Aspergillosis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;63(4):e1-60.
13. Tolsura Prescribing Information. Mayne Pharma; Greenville, NC. June 2020.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. September 2022.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. April 2021.

17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. December 2021.
18. Vfend Prescribing Information. Roerig. New York, NY. October 2021.

Balversa (erdafitinib)

Prior Authorization Guideline

Guideline Name	Balversa (erdafitinib)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Balversa (erdafitinib)
Urothelial Carcinoma Indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC) that has susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations and progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

2 . Criteria

Product Name: Balversa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of urothelial carcinoma

AND

2 - One of the following:

- Locally advanced
- Metastatic

AND

3 - Patient has fibroblast growth factor receptor (FGFR) 3 or FGFR2 genetic alterations as detected by a U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Patient has progressed during or following at least one line of prior platinum-containing chemotherapy (e.g., gemcitabine with cisplatin or carboplatin, dose dense methotrexate vinblastine doxorubicin cisplatin [DDMVAC] with growth factor support, etc.) [2]

OR

4.2 Patient has progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (e.g., [DDMVAC] with growth factor support, gemcitabine with cisplatin, etc.) [2]

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Balversa

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Balversa Prescribing Information. Janssen Products. Horsham, PA. July 2020.
2. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in Oncology: Bladder Cancer v1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf. Accessed April 5, 2022.

Banzel (rufinamide)

Prior Authorization Guideline

Guideline Name	Banzel (rufinamide)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Banzel (rufinamide) tablets and oral suspension
Lennox-Gastaut Syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome in pediatric patients 1 year of age and older and in adults.

2 . Criteria

Product Name: Banzel (rufinamide) tablets and suspension	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)	

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - Both of the following:

4.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate)

AND

4.2 Trial and failure, or intolerance to generic rufinamide

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic rufinamide	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)	

AND

2 - Used as adjunctive therapy

AND

3 - Patient is 1 year of age or older

AND

4 - One of the following:

4.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate) other than generic rufinamide

OR

4.2 For continuation of prior therapy if the patient is established on generic rufinamide

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Banzel and generic rufinamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Banzel Prescribing Information. Eisai Inc. Woodcliff, NJ. November 2020.

Beleodaq (belinostat)

Prior Authorization Guideline

Guideline Name	Beleodaq (belinostat)
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Beleodaq (belinostat)
Peripheral T-Cell Lymphoma (PTCL) Indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

2 . Criteria

Product Name: Beleodaq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of peripheral T-cell lymphoma (PTCL) [2]

AND

2 - Disease is relapsed or refractory

AND

3 - Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy, stem cell transplant)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Beleodaq

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Beleodaq Prescribing Information. Spectrum Pharmaceuticals, Inc.; Irvine, CA. January 2020.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. T-cell Lymphomas. v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf. Accessed February 1, 2021.

Prior Authorization Guideline

Guideline Name	Benlysta (belimumab)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.
Lupus Nephritis Indicated for the treatment of patients aged 5 years and older with active lupus nephritis who are receiving standard therapy. Limitations of Use: The efficacy of Benlysta has not been evaluated in patients with severe active central nervous system lupus. Use of Benlysta is not recommended in these situations.

2 . Criteria

Product Name: Benlysta SC	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active systemic lupus erythematosus (SLE)</p> <p style="text-align: center;">AND</p> <p>2 - Autoantibody positive (i.e., anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL) [2, 3]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to two standard of care treatments for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [5]</p> <p style="text-align: center;">AND</p> <p>5 - Currently receiving at least one standard of care treatment for active SLE (e.g., antimalarials [e.g., Plaquenil (hydroxychloroquine)], corticosteroids [e.g., prednisone], or immunosuppressants [e.g., methotrexate, Imuran (azathioprine)]) [2, 3]</p> <p style="text-align: center;">AND</p> <p>6 - Prescribed by or in consultation with a rheumatologist</p>	

Product Name: Benlysta SC	
Diagnosis	Lupus nephritis

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active lupus nephritis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Nephrologist • Rheumatologist 	

Product Name: Benlysta SC	
Diagnosis	All indications listed above
Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., decrease or stabilization of</p>	

symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

3 . Endnotes

- A. SLE is a disease that fluctuates. The undulating course of typical lupus patients requires frequent reassessment. A 6-month authorization period is reasonable. [2]

4 . References

1. Benlysta Prescribing Information. GlaxoSmithKline LLC. Philadelphia, PA. July 2022.
2. Per clinical consult with rheumatologist, October 4, 2017.
3. American College of Rheumatology Ad Hoc Committee on Systemic Lupus Erythematosus Guidelines. Guidelines for referral and management of systemic lupus erythematosus. *Arthritis Rheum.* 1999 Sep;42(9):1785-96.
4. American College of Rheumatology Guidelines for Screening, Case Definition, Treatment and Management of Lupus Nephritis. *Arthritis Care Res (Hoboken).* 2012 Jun; 64(6): 797-808.
5. Fanouriakis A, Kostopoulou M, Alunno A, et al. *Ann Rheum Dis* 2019;78:736–745.

Prior Authorization Guideline

Guideline Name	Besremi (ropeginterferon alfa-2b-njft) - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Besremi (ropeginterferon alfa-2b-njft)
Polycythemia Vera Indicated for the treatment of adults with polycythemia vera.

2 . Criteria

Product Name: Besremi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of polycythemia vera as confirmed by all of the following [A]:	
1.1 One of the following:	

- Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women
- Hematocrit greater than 49% for men or hematocrit greater than 48% for women
- Increased red cell mass

AND

1.2 Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes

AND

1.3 One of the following:

- Presence of JAK2 or JAK2 exon 12 mutation
- Subnormal serum erythropoietin level

AND

2 - Both of the following: [2, 3, 4, 5]

2.1 Trial and failure, contraindication or intolerance to hydroxyurea

AND

2.2 Trial and failure, contraindication or intolerance to one interferon therapy (e.g., Intron A, Pegasys, etc.)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Besremi

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., improvement in hematological response, resolution of splenomegaly, absence of thromboembolic events) [2]</p>	

Product Name: Besremi	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of polycythemia vera as confirmed by all of the following [A]:</p> <p>1.1 One of the following:</p> <ul style="list-style-type: none"> • Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women • Hematocrit greater than 49% for men or hematocrit greater than 48% for women • Increased red cell mass <p style="text-align: center;">AND</p> <p>1.2 Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes</p> <p style="text-align: center;">AND</p> <p>1.3 One of the following:</p> <ul style="list-style-type: none"> • Presence of JAK2 or JAK2 exon 12 mutation • Subnormal serum erythropoietin level 	

AND

2 - Both of the following: [2, 3, 4, 5]

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to hydroxyurea

AND

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to one interferon therapy (e.g., Intron A, Pegasys, etc.)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

3 . Endnotes

- A. According to the World Health Organization (WHO), diagnosis of polycythemia vera requires meeting either all three major criteria or the first two major criteria and one minor criterion. The three major criteria are as follows: 1) Hemoglobin > 16.5 g/dL for men or hemoglobin > 16.0 g/dL for women, or Hematocrit > 49% for men or Hematocrit > 48% for women, or increased red cell mass; 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes (differences in size); 3) Presence of JAK2 or JAK2 exon 12 mutation. The minor criterion is subnormal serum erythropoietin level. [3]

4 . References

1. BESREMi (ropeginterferon alfa-2b-njft) [Prescribing Information]. Taipei, Taiwan. PharmaEssentia Corporation. November 2021.
2. Vannucchi A, Barbui T, Cervantes F et al. Philadelphia chromosome-negative chronic myeloproliferative neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology*. 2015;26:v85-v99.
3. Barbui T, Thiele J, Gisslinger H et al. The 2016 WHO classification and diagnostic criteria for myeloproliferative neoplasms: document summary and in-depth discussion. *Blood Cancer J*. 2018;8(2)

4. Abu-Zeinah, G., Krichevsky, S., Cruz, T. et al. Interferon-alpha for treating polycythemia vera yields improved myelofibrosis-free and overall survival. *Leukemia* 35, 2592–2601 (2021).
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Myeloproliferative Neoplasms v2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf. Accessed December 29, 2021.

Prior Authorization Guideline

Guideline Name	Blood Glucose Test Strips
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit
Approval Criteria 1 - Physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions) [A]	

2 . Endnotes

- A. The evidence regarding the utility and optimal frequency of self-monitoring of blood glucose (SMBG) is not well defined for patients who do not use intensive insulin regimens, such as those with type 2 diabetes using oral agents and/or basal insulin [1]. However for most patients using intensive insulin regimens (multiple-dose insulin or

insulin pump therapy) SMBG should be performed prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.

3 . References

1. American Diabetes Association (ADA). Standards of medical care in diabetes (2018). *Diabetes Care*. 2018;41(suppl 1):S1-S156.

Bosulif (bosutinib)

Prior Authorization Guideline

Guideline Name	Bosulif (bosutinib)
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Bosulif (bosutinib)
Resistant or intolerant Chronic Myelogenous/Myeloid Leukemia Indicated for the treatment of adult patients with chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or intolerance to prior therapy.
Newly-diagnosed Chronic Myelogenous Leukemia Indicated for the treatment of adult patients with newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).

2 . Criteria

Product Name: Bosulif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive chronic myelogenous/myeloid leukemia (Ph+ CML) [1,2]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Trial and failure or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

Product Name: Bosulif	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Bosulif therapy	

3 . References

1. Bosulif Prescribing Information. Pfizer. New York, NY. May 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on March 18, 2020.

Prior Authorization Guideline

Guideline Name	Botox (onabotulinumtoxinA)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Botox (onabotulinumtoxin A)
<p>Overactive Bladder Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.</p> <p>Detrusor Overactivity associated with a Neurologic Condition Indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.</p> <p>Neurogenic Detrusor Overactivity (NDO) Indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 5 years of age and older who have an inadequate response to or are intolerant of anticholinergic medications.</p> <p>Chronic Migraine Indicated for the prophylaxis of headaches in adult patients with chronic migraine (greater than or equal to 15 days per month with headache lasting 4 hours a day or longer). Important Limitations: Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.</p> <p>Spasticity Indicated for the treatment of spasticity in patients 2 years of age and older. Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.</p>

Cervical Dystonia (Spasmodic Torticollis) Indicated for the treatment of cervical dystonia in adults to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

Primary Axillary Hyperhidrosis Indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents. Limitations: The safety and effectiveness of Botox for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive Botox for palmar hyperhidrosis and facial hyperhidrosis, respectively. Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease. Safety and effectiveness of Botox have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

Blepharospasm and strabismus Indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders (involving muscles of the face) in patients 12 years of age and above.

Off Label Uses: Chronic Low Back Pain [2, 3] Used in the treatment of chronic low back pain.

Other Uses [2, 3] Used in the treatment of achalasia, chronic anal fissures, dynamic muscle contracture in pediatric cerebral palsy patients, sialorrhea, hand tremor, and oromandibular dystonia.

Drug Name: Botox Cosmetic (onabotulinumtoxin A)

Cosmetic Uses [Non-approvable Use] Indicated in adult patients for the temporary improvement in the appearance of: 1) Moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity 2) Moderate to severe lateral canthal lines associated with orbicularis oculi activity 3) Moderate to severe forehead lines associated with frontalis muscle activity ****Please Note:** The request for Botox (onabotulinumtoxin A) injections to treat the appearance of facial lines is not authorized given that this use is for cosmetic purposes only.

2 . Criteria

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Neuromuscular and Autonomic Disorders
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 One of the following:

1.1.1 ALL of the following:

- Diagnosis of blepharospasm associated with dystonia (e.g., benign essential blepharospasm)
- Patient is 18 years of age or older
- Trial and failure, contraindication or intolerance to Xeomin

OR

1.1.2 Patient is 12 thru 17 years of age

OR

1.2 Both of the following:

1.2.1 Diagnosis of cervical dystonia (also known as spasmodic torticollis)

AND

1.2.2 Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

OR

1.3 Both of the following:

1.3.1 Diagnosis of upper limb spasticity

AND

1.3.2 Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

OR

1.4 Both of the following:

1.4.1 Diagnosis of lower limb spasticity

AND

1.4.2 Trial and failure, contraindication or intolerance to Dysport

OR

1.5 Diagnosis of strabismus

OR

1.6 Diagnosis of VII cranial nerve disorders (hemifacial spasms)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Blepharospasm Associated with Dystonia
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - One of the following:

3.1 Both of the following:

- Patient is 18 years of age or older
- Trial and failure, contraindication or intolerance to Xeomin

OR

3.2 Patient is 12 thru 17 years of age

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Cervical Dystonia
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport
- Myobloc

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Upper Limb Spasticity
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Approval Length	3 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have or will have elapsed since the last treatment

AND

3 - Trial and failure, contraindication or intolerance to one of the following:

- Xeomin
- Dysport

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Lower Limb Spasticity
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Approval Length	3 month(s)
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Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have or will have elapsed since the last treatment</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication or intolerance to Dysport</p>	

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Strabismus, VII Cranial Nerve Disorders
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have or will have elapsed since the last treatment</p>	

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of primary axillary hyperhidrosis [G]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) [A, 1, 4]</p> <p style="text-align: center;">OR</p> <p> 2.2 Skin maceration with secondary infection [5]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]</p>	

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - At least a 2-point improvement in HDSS [1, 4]</p>	

AND

2 - At least 3 months have or will have elapsed since the last series of injections [1, 4]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic migraines [I]</p> <p>AND</p> <p>2 - Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [M]</p> <p>AND</p> <p>3 - Patient is 18 years of age or older [N]</p> <p>AND</p> <p>4 - Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [1, 13-16, L]</p> <p>AND</p> <p>5 - Prescribed by or in consultation with one of the following specialists:</p>	

- Neurologist
- Pain specialist
- Headache specialist

AND

6 - Two of the following: [H, J, O, P, Q, R]

6.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

6.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

6.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol

OR

6.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

7 - Trial and failure, contraindication or intolerance to one of the following:

- Aimovig
- Ajovy

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity [19]</p> <p style="text-align: center;">AND</p> <p>2 - Use of acute migraine medications (e.g., NSAIDS, triptans) has decreased since the start of therapy</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following specialists:</p> <ul style="list-style-type: none">• Neurologist• Pain specialist• Headache specialist <p style="text-align: center;">AND</p> <p>4 - Patient continues to be monitored for medication overuse headache (MOH) [M]</p>	

AND

5 - Trial and failure, contraindication or intolerance to one of the following:

- Aimovig
- Ajovy

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Urinary Incontinence associated with a Neurologic Condition OR Overactive Bladder with Symptoms OR Neurogenic Detrusor Overactivity (NDO)
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Approval Length	3 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - One of the following conditions: [1, 3, E, F]

- Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis)
- Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency)
- Neurogenic detrusor overactivity (NDO)

AND

2 - Prescribed by or in consultation with a urologist

AND

3 - Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)]

AND

4 - Patient is routinely performing clean intermittent self-catheterization (CIC) or is willing/able to perform CIC if he/she has post-void residual (PVR) urine volume greater than 200 mL

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Urinary Incontinence associated with a Neurologic Condition OR Overactive Bladder with Symptoms OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient demonstrates positive clinical response to therapy	
AND	
2 - At least 3 months have or will have elapsed since the last treatment	

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic anal fissure [8, 9]	

AND

2 - At least 2 months of one of the following symptoms:

- Nocturnal pain and bleeding
- Postdefecation pain

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:

- Topical nitrates (e.g. Glyceryl trinitrate (Nitroglycerin))
- Topical calcium channel blockers (CCBs) (e.g., diltiazem, nifedipine)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
<ul style="list-style-type: none">• Incomplete healing of fissure• Recurrence of fissure	
AND	
2 - Patient demonstrates positive clinical response to therapy	
AND	

3 - At least 3 months have or will have elapsed since the last series of injections

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis | Chronic Back Pain [D] (Off-Label)

Approval Length | 1 treatment session (series of injections) [K]

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of low back pain

AND

2 - Low back pain has lasted for greater than or equal to six (6) months

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Neurosurgeon
- Orthopedist
- Pain specialist

AND

4 - Trial and failure (at least 3 months), contraindication, or intolerance to both of the following conventional therapies: [10-12]

- At least one oral NSAID medication
- At least one opioid medication

AND

5 - Trial and failure or inadequate response to one of the following: [10]

- Physical therapy
- Nonpharmacologic therapy (e.g., spinal manipulation, massage therapy, transcutaneous electrical nerve stimulation (TENS), acupuncture/acupressure, and surgery)

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have or will have elapsed since the last series of injections</p> <p style="text-align: center;">AND</p> <p>3 - Treatment has not exceeded two treatment sessions total per year</p>	
Notes	Authorization will not exceed more than two treatment sessions total per year (including initial authorization).

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of achalasia

AND

2 - One of the following:

2.1 High risk of complication from or failure to one of the following: [6, 7]

- Pneumatic dilation
- Myotomy

OR

2.2 Prior dilation caused esophageal perforation

OR

2.3 Patient has an increased risk of dilation-induced perforation due to one of the following:

- Epiphrenic diverticulum
- Hiatal hernia

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates improvement or reduction in symptoms of achalasia (i.e., dysphagia, regurgitation, chest pain)

AND

2 - At least 6 months have or will have elapsed since the last series of injections [C]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	All other diagnoses
Approval Length	6 months unless the FDA-approved treatment duration is less than 6 months. If FDA-approved treatment duration is less than 6 months, utilize the FDA-approved duration for authorization period.
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert)</p> <p>AND</p> <p>1.1.2 Additional requirements listed in the "Indications and Usage" and "Dosage and Administration" sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc)</p> <p>OR</p> <p>1.2 Meets the off-label administrative guideline criteria</p> <p>AND</p>	

2 - Trial and failure, contraindication, or intolerance to two appropriate formulary alternatives (if available)

Product Name: All Products

Diagnosis Cosmetic Use

Guideline Type Prior Authorization

Approval Criteria

1 - Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.

3 . Endnotes

- A. Hyperhidrosis Disease Severity Scale • The HDSS is a 4-point scale designed to assess the severity of hyperhidrosis in everyday clinical practice or in clinical research and the effectiveness of treatment. • The HDSS can be administered by an interviewer or self-completed by the patient. • The HDSS assess disease severity based on the extent of sweating-related impairment of daily activities. (1) Question - My (underarm) sweating is never noticeable and never interferes with my daily activities, Score - 1; (2) Question - My (underarm) sweating is tolerable but sometimes interferes with my daily activities, Score - 2; (3) Question - My (underarm) sweating is barely tolerable and frequently interferes with my daily activities, Score - 3; (4) Question - My (underarm) sweating is intolerable and always interferes with my daily activities, Score - 4
- B. This recommendation is based on results from the PREEMPT 2 trial. The primary endpoint of PREEMPT 2 was the mean change from baseline in frequency of headache days for the 28-day period ending with week 24. [13, 14]
- C. Approximately 50% of achalasia patients relapse and require repeat treatments at 6 to 24-month intervals. [6]
- D. An evidence-based review by the American Academy of Neurology (AAN) concluded that botulinum neurotoxin (BoNT) is possibly effective for the treatment of chronic predominantly unilateral low back pain (LBP) [one Class II study]. The AAN recommends that BoNT may be considered as a treatment option for patients with chronic predominantly unilateral LBP (Level C). [12]
- E. An evidence-based review by the AAN established BoNT as safe and effective for the treatment of neurogenic detrusor overactivity (NDO) in adults (one Class I study and one Class II study). Data on the use of BoNT is probably safe and effective for the treatment of detrusor sphincter dyssynergia (DSD) in patients with spinal cord injury (2 Class II studies). On basis of one Class I study, BoNT does not provide significant benefit for the treatment of DSD in patients with multiple sclerosis (MS). The AAN recommends that BoNT should be offered as a treatment option for neurogenic detrusor overactivity (Level

- A), and that BoNT should be considered for DSD in patients with spinal cord injury (Level B). [12]
- F. BoNT is not effective in patients with DSD due to multiple sclerosis in a multicenter, double-blind, placebo-controlled trial; however, in patients with DSD due to spinal cord injury, open-label clinical studies showed improvements in urodynamic parameters [recommendation for DSD: Adult, Class IIb, Category B]. For NDO, the use of BoNT (refractory to antispasmodics) in a randomized, double-blind, placebo-controlled clinical trial of 59 patients (n = 53 with spinal cord injury and n = 6 with multiple sclerosis) showed significant improvement in daily incontinence episodes in weeks 1 through 24 (except for weeks 12 and 18) compared to placebo [recommendation for NDO: Adult, Class IIb, Category B]. [12]
 - G. The safety and effectiveness of Botox for hyperhidrosis in areas other than the axillae have not been established. [1]
 - H. Clinical benefit from prophylactic therapy may take as long as 2 to 3 months to manifest. [17, 18] Recommended first-line agents for the prevention of migraine headache are atenolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, divalproex sodium, and sodium valproate. [17]
 - I. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. [1] An evidence-based review by the American Academy of Neurology determined that, based on available evidence, Botox was probably ineffective in episodic migraine and tension-type headaches, and should not be considered in patients with these conditions. [12]
 - J. The effects of Botox in reducing the frequency of headache days in the PREEMPT trial and in the pooled analysis of the PREEMPT trials were very modest. Given the experience and evidence we have for other prophylactic treatments in the management of migraine, which are supported by national guidelines, it is reasonable to require failure with other prophylactic treatments before approving use of Botox. [17]
 - K. A single small randomized trial (n = 31) compared paravertebral injections of botulinum toxin with saline injections and found significant benefit of botulinum toxin up to eight weeks after injection. There is currently no consensus on number of injections or treatment length for low back pain. [12]
 - L. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [20]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
 - M. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [20]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
 - N. The safety and effectiveness of Botox for chronic headache in patients below the age of 18 years have not been established. In a 12-week, multicenter, double-blind, placebo-controlled clinical trial, 123 adolescent patients (ages 12 to below 18 years) with chronic migraine were randomized to receive Botox 74 Units, Botox 155 Units, or placebo, for one injection cycle. This trial did NOT establish the efficacy of Botox, compared with placebo, for the prophylaxis of headaches in adolescents with chronic migraine. [1]
 - O. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e.,

Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [21]. They also support the use of Botox (onabotulinumtoxin A) as an efficacious treatment option for chronic migraine. Botox (onabotulinumtoxin A) is not however recommended for episodic migraine treatment.

- P. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [17]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
- Q. The OptumRx clinical team consulted with a neurologist [22]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors.
- R. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [23].

4 . References

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Braftovi (encorafenib)

Prior Authorization Guideline

Guideline Name	Braftovi (encorafenib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Braftovi (encorafenib)
BRAF V600E or V600K unresectable or metastatic melanoma Indicated in combination with Mektovi (binimetinib) for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation, as detected by an FDA-approved test. Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.
Colorectal Cancer (CRC) Indicated in combination with Erbitux (cetuximab) for the treatment of adult patients with metastatic colorectal cancer with BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy. Limitations of Use: Braftovi is not indicated for treatment of patients with wild-type BRAF melanoma or wild-type BRAF CRC.

2 . Criteria

Product Name: Braftovi	
Diagnosis	Melanoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses: [2]</p> <ul style="list-style-type: none"> • Unresectable melanoma • Metastatic melanoma <p style="text-align: center;">AND</p> <p>2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with Mektovi (binimetinib)</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication or intolerance to one of the following:</p> <ul style="list-style-type: none"> • Zelboraf • Tafinlar <p style="text-align: center;">OR</p> <p>4.2 For continuation of prior therapy</p>	

Product Name: Braftovi	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none"> • Colon Cancer • Rectal Cancer <p style="text-align: center;">AND</p> <p>2 - One of the following [3,4]:</p> <ul style="list-style-type: none"> • Unresectable or advanced disease • Metastatic disease <p style="text-align: center;">AND</p> <p>3 - Patient has received prior therapy</p> <p style="text-align: center;">AND</p> <p>4 - Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>5 - Used in combination with Erbitux (cetuximab)</p>	

Product Name: Braftovi	
Diagnosis	Melanoma and Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

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Bronchitol (mannitol) inhalation powder

Prior Authorization Guideline

Guideline Name	Bronchitol (mannitol) inhalation powder
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Bronchitol (mannitol) inhalation powder
Cystic Fibrosis (CF) Indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years and older with cystic fibrosis. Use only in adults who have passed the Bronchitol Tolerance Test.

2 . Criteria

Product Name: Bronchitol	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient is 18 years of age or older	

AND

2 - Diagnosis of cystic fibrosis (CF)

AND

3 - Patient has passed the Bronchitol Tolerance Test (BTT)

AND

4 - One of the following:

4.1 Patient is currently receiving Pulmozyme (dornase alfa)

OR

4.2 Patient has a contraindication, intolerance, or is not a candidate for continued Pulmozyme therapy

AND

5 - Trial and failure, contraindication, or intolerance to inhaled hypertonic saline

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Specialist affiliated with a CF care center

Product Name: Bronchitol

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., improvement in lung function [forced expiratory volume in one second {FEV1}])</p>	

3 . References

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Prior Authorization Guideline

Guideline Name	Brukina (zanubrutinib)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Brukina (zanubrutinib)
<p>Mantle Cell Lymphoma Indicated for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> <p>Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma Indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma [6]</p> <p>Marginal Zone Lymphoma Indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.</p> <p>Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).</p>

2 . Criteria

Product Name: Brukinsa	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of relapsed or refractory mantle cell lymphoma (MCL)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has received at least one prior therapy for MCL</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist/hematologist</p>	

Product Name: Brukinsa	
Diagnosis	Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma [6]</p> <p style="text-align: center;">AND</p>	

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brukinsa

Diagnosis	Marginal Zone Lymphoma (MZL)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of Marginal Zone Lymphoma (MZL)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brukinsa

Diagnosis	Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of ONE of the following:

- Chronic Lymphocytic Leukemia (CLL)
- Small Lymphocytic Lymphoma (SLL)

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Brukinsa

Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. Chemotherapy regimens may include bendamustine; cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP); cyclophosphamide, vincristine, prednisone (CVP); fludarabine, cyclophosphamide, mitoxantrone (FCM).

4 . References

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Bylvay (odevixibat)

Prior Authorization Guideline

Guideline Name	Bylvay (odevixibat)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Bylvay (odevixibat)
Pruritus associated with progressive familial intrahepatic cholestasis (PFIC) Indicated for the treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC). Limitation of Use: Bylvay may not be effective in PFIC type 2 patients with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3).
Alagille syndrome Indicated for the treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome.

2 . Criteria

Product Name: Bylvay	
Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 confirmed by one of the following: [B-D, 2]

- Diagnostic test (e.g., liver function test, liver ultrasound and biopsy, bile analysis)
- Genetic Testing

AND

2 - Patient is experiencing both of the following: [1]

- Moderate to severe pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient is 3 months of age or older

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [6]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg [A, 3]

AND

6 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay

Diagnosis	Progressive Familial Intrahepatic Cholestasis (PFIC)
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Approval Length	12 Months
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduced serum bile acids, improved pruritus)

AND

2 - Prescribed dose is consistent with FDA-approved package labeling and does not exceed a total daily dose of 6 mg [A, 3]

Product Name: Bylvay

Diagnosis	Alagille Syndrome (ALGS)
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Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [E, 7, 9]

AND

2 - Patient is experiencing both of the following: [10]

- Moderate to severe cholestatic pruritus
- Patient has a serum bile acid concentration above the upper limit of the normal reference for the reporting laboratory

AND

3 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [F, 7-8]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

4 - Patient is 12 months of age or older

AND

5 - Prescribed by or in consultation with a hepatologist or gastroenterologist

Product Name: Bylvay	
Diagnosis	Alagille Syndrome (ALGS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient demonstrates positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)

3 . Definitions

Definition	Description
PFIC	PFIC:[2] Progressive: tending to get worse over time; Familial: originally described in families and related to changes in genes; Intrahepatic: involves disease inside the liver; Cholestasis: means poor bile flow and build-up of substances in the liver that would normally be carried out of the liver into bile and then the intestines

4 . Endnotes

- A. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg [3].
- B. The efficacy of BYLVAY was evaluated in Trial 1 (NCT03566238), a 24-week, randomized, double-blind, placebo-controlled trial. Trial 1 was conducted in 62 pediatric patients, aged 6 months to 17 years, with a confirmed molecular diagnosis of PFIC type 1 or type 2, and presence of pruritus at baseline. [3]
- C. Trial 2 is a 72-week, open-label, single-arm trial in PFIC type 1, 2, and 3 patients. [3]
- D. Diagnostic testing may include liver functions tests, liver ultrasound and biopsy, and/or bile analysis. Genetic testing may be used in selected patients to confirm diagnosis and distinguish type. All 3 subtypes of PFIC have increased serum bile acid levels. [5]
- E. Alagille Syndrome is an autosomal dominant disease with variable expressivity, caused by heterozygous mutations in either JAG1 or NOTCH2. The vast majority of cases are due to JAG1 mutations accounting for 94%, and NOTCH2 mutations in additional 2–4%. [7]
- F. The management of pruritus in ALGS is challenging, and a variety of therapies are often used. These include antihistamines, rifampin, ursodeoxycholic acid, cholestyramine, naltrexone, and sertraline. Clinical experience suggests that these drugs have variable efficacy in reducing pruritus; however, no prospective clinical trials has quantified the effect of any of these therapies, either alone or in combination. [8]

5 . References

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2. PFIC Advocacy and Resource Network, Inc. Available at <https://www.pfic.org/types-and-subtypes-of-pfic/> Accessed August 5, 2021.
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Cablivi (caplacizumab-yhdp)

Prior Authorization Guideline

Guideline Name	Cablivi (caplacizumab-yhdp)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombocytic Thrombocytopenic Purpura (aTTP) Indicated for the treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy.

2 . Criteria

Product Name: Cablivi	
Diagnosis	Acquired Thrombocytic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acquired thrombocytic thrombocytopenic purpura (aTTP)	

AND

2 - First dose was/will be administered by a healthcare provider as a bolus intravenous injection

AND

3 - Used in combination with immunosuppressive therapy (e.g., rituximab, glucocorticoids) [3]

AND

4 - One of the following:

4.1 Used in combination with plasma exchange

OR

4.2 Both of the following:

- Patient has completed plasma exchange
- Less than 59 days have or will have elapsed beyond the last plasma exchange [B]

AND

5 - Prescribed by or in consultation with a hematologist or oncologist[2]

3 . Endnotes

- A. Three month approval duration, based on package insert stating longest therapy in trial was 77 days.
- B. Per package insert, after the plasma exchange period can use injection once daily for 30 days beyond the last plasma exchange and after the initial treatment course, if signs of persistent underlying disease are present treatment can be extended for a maximum of 28 days, totaling 58 days of therapy after last plasma exchange.

4 . References

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Available at:
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm>.
Accessed March 14, 2019.

Prior Authorization Guideline

Guideline Name	Cabometyx (cabozantinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Cabometyx (cabozantinib) tablets
Renal cell carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC).
Renal cell carcinoma (RCC) Indicated, in combination with nivolumab, for the first-line treatment of patients with advanced RCC.
Hepatocellular Carcinoma (HCC) Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
Differentiated Thyroid Cancer Indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible.

2 . Criteria

Product Name: Cabometyx

Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of renal cell carcinoma (RCC)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is advanced</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Oncologist • Nephrologist 	

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hepatocellular carcinoma (HCC)</p> <p style="text-align: center;">AND</p>	

2 - Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate)*

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

Notes

*Criterion is part of the FDA-approved label

Product Name: Cabometyx

Diagnosis Differentiated Thyroid Cancer (DTC)

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid cancer (DTC) [A, 5]

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Patient is 12 years of age or older

AND

4 - Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib])*

AND

5 - Disease or patient is refractory to radioactive iodine treatment or ineligible

AND

6 - Prescribed by or in consultation with an oncologist

Notes

*Criterion is part of the FDA-approved label

Product Name: Cabometyx	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Differentiated thyroid carcinomas are broadly categorized as papillary thyroid carcinoma (PTC), follicular cancer (FTC), and Hurthle cell carcinoma (HCTC). [5]

4 . References

1. Cabometyx Prescribing Information. Exelixis, Inc. San Francisco, CA. January 2023.
2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Kidney Cancer. Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed January 29, 2021.
3. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Hepatocellular Carcinoma. Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf Accessed May 3, 2023.
4. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 29, 2019.
5. Patel K, Yip L, Lubitz C et al. The American Association of Endocrine Surgeons Guidelines for the Definitive Surgical Management of Thyroid Disease in Adults. *Ann Surg.* 2020;271(3):e21-e93.

Prior Authorization Guideline

Guideline Name	Cabotegravir Containing Agents - PA, NF
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Cabenuva (cabotegravir and rilpivirine) Injection
Treatment of HIV-1 Infection Indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.
Drug Name: Vocabria (cabotegravir) Tablet
Treatment of HIV-1 Infection Indicated in combination with EDURANT (rilpivirine) for short-term treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 35kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Cabenuva extended-release injectable suspension for HIV-1 treatment. 2) Oral therapy for patients who will miss planned injection dosing with Cabenuva for HIV-1 treatment.
HIV-1 Pre-Exposure Prophylaxis Indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude extended-release injectable suspension for

HIV-1 PrEP. 2) Oral therapy for patients who will miss planned injection dosing with Apretude for HIV-1 PrEP.

Drug Name: Apretude (cabotegravir) Injection

HIV-1 Pre-exposure prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test prior to initiating Apretude (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP.

2 . Criteria

Product Name: Vocabria*, Cabenuva*

Diagnosis	Treatment of HIV-1 Infection
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Approval Length	12 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Cabenuva at GPI list "CABOTTEGRPA".
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Product Name: Vocabria*, Cabenuva*

Diagnosis	Treatment of HIV-1 Infection
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

1.3 Patient's weight is greater than or equal to 35 kg

AND

1.4 Patient is currently virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable, uninterrupted antiretroviral regimen for at least 6 months

AND

1.5 Patient has no history of treatment failure or known/suspected resistance to either cabotegravir or rilpivirine

AND

1.6 Provider attests that patient would benefit from long-acting injectable therapy over standard oral regimens

AND

1.7 Prescribed by or in consultation with a clinician with HIV expertise

OR

2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]

Notes

*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list "CABOTTEGRPA".

Product Name: Vocabria**, Apretude**

Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - One of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Provider attests to both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list "APREUDEPA"
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Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:</p> <ul style="list-style-type: none"> • Negative HIV-1 antigen/antibody test • Negative HIV-1 RNA assay 	
Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list "APREUDEPA"

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection</p>	

AND

2 - Patient's weight is greater than or equal to 35 kg

AND

3 - Submission of medical records (e.g., chart notes) confirming documentation of both the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg

OR

4.2 Both of the following:

- Patient would benefit from long-acting injectable therapy over standard oral regimens
- Patient would be adherent to testing and dosing schedule

Notes

**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list "APRETUDEPA"

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Provider attests that patient is adherent to the testing appointments and scheduled injections of Apretude

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to each maintenance injection of Apretude for HIV PrEP:

- Negative HIV-1 antigen/antibody test
- Negative HIV-1 RNA assay

Notes

**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list "APREUDEPA"

3 . Endnotes

- A. Continuation of therapy for Cabenuva and Vocabria in NF criteria will allow for a 70-day gap to account for the 2-month dosing schedule +/- 7 days. [1]

4 . References

1. Cabenuva Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. April 2022.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. March 2022.
3. Apretude Prescribing information. ViiV Healthcare Company. Research Triangle Park, NC. December 2021.

Prior Authorization Guideline

Guideline Name	Calquence (acalabrutinib)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Calquence (acalabrutinib)
Mantle Cell Lymphoma (MCL) Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.
Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

2 . Criteria

Product Name: Calquence	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Patient has received at least one prior therapy for MCL

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist

Product Name: Calquence	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Calquence	
Diagnosis	Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia or small lymphocytic lymphoma

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist

Product Name: Calquence	
Diagnosis	Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Calquence Capsule Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2022.
2. Calquence Tablet Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. August 2022.

Prior Authorization Guideline

Guideline Name	Camzyos (mavacamten) - PA, NF
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Camzyos (mavacamten)
Obstructive hypertrophic cardiomyopathy (HCM) Indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

2 . Criteria

Product Name: Camzyos	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)	

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Patient has valsalva left ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: [2]

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy (e.g., improved symptom relief)

AND

2 - Patient has a left ventricular ejection fraction of greater than or equal to 50% [A,B,1]

AND

3 - Prescribed by or in consultation with a cardiologist

Product Name: Camzyos

Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of obstructive hypertrophic cardiomyopathy (HCM)

AND

2 - Patient has New York Heart Association (NYHA) Class II or III symptoms (e.g., shortness of breath, chest pain)

AND

3 - Submission of medical records (e.g., chart notes) documenting patient has a left ventricular ejection fraction of greater than or equal to 55%

AND

4 - Submission of medical records (e.g., chart notes) documenting patient has valsalva left

ventricular outflow tract (LVOT) peak gradient greater than or equal to 50 mmHg at rest or with provocation

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following at a maximally tolerated dose: [2]

- non-vasodilating beta blocker (e.g., bisoprolol, propranolol)
- calcium channel blocker (e.g., verapamil, diltiazem)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Camzyos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., improved symptom relief)	
AND	
2 - Submission of medical records (e.g., chart notes) documenting patient has a left ventricular ejection fraction of greater than or equal to 50% [A,B,1]	
AND	
3 - Prescribed by or in consultation with a cardiologist	

3 . Endnotes

- A. Patients may develop heart failure while taking CAMZYOS. Regular LVEF and Valsalva left ventricular outflow tract (LVOT) gradient assessment is required for careful titration to achieve an appropriate target Valsalva LVOT gradient, while maintaining LVEF $\geq 50\%$ and avoiding heart failure symptoms. [1]
- B. If LVEF $< 50\%$ while taking Camzyos, interrupt treatment. [1]

4 . References

1. Camzyos prescribing information. MyoKardia, Inc. Brisbane, CA. April 2022.
2. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients With Hypertrophic Cardiomyopathy. *Circulation*. 2020;142(25).

Prior Authorization Guideline

Guideline Name	Cannabinoids
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
<p>Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.</p> <p>Anorexia in patients with AIDS Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS)</p>

2 . Criteria

Product Name: Brand Marinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes

*This product may require prior authorization.

Product Name: Syndros

Diagnosis

Chemotherapy-induced nausea and vomiting

Approval Length

6 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - One of the following:

2.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

2.2 Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes

*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol

Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - Trial and failure or intolerance to formulary generic dronabinol capsules*

Notes

*This product may require prior authorization.

Product Name: Syndros

Diagnosis

Anorexia in Patients with AIDS

Approval Length

3 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - One of the following:

4.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

4.2 Patient is unable to swallow capsules

Notes

*This product may require prior authorization.

Product Name: Generic dronabinol

Diagnosis | Anorexia in Patients with AIDS

Approval Length | 3 month(s)

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

3 . Endnotes

- A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT₃ receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed March 9, 2022.
2. Marinol prescribing information. Patheon Softgels, Inc. High Point, NC. March 2021.
3. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.
4. American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc*. 2019;00:1-21.
5. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. *J Pain Symptom Manage* 2004;27:360-369.
6. Per clinical consult with HIV specialist, February 4, 2013.
7. Syndros prescribing information. Benuvia Therapeutics, Inc. Chandler, AZ. January 2021.
8. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. *Am Fam Physician*. 1999;60(3):843-854.
9. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in

patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

Prior Authorization Guideline

Guideline Name	Cannabinoids
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Guideline Note:

Effective Date:	5/1/2022
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1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
<p>Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.</p> <p>Anorexia in patients with AIDS Indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS.</p>

2 . Criteria

Product Name: Brand Marinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes

*This product may require prior authorization.

Product Name: Syndros

Diagnosis

Chemotherapy-induced nausea and vomiting

Approval Length

6 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - One of the following:

2.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

2.2 Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes

*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is receiving cancer chemotherapy

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol

Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to Megace (megestrol)

AND

4 - Trial and failure or intolerance to formulary generic dronabinol capsules*

Notes

*This product may require prior authorization.

Product Name: Syndros

Diagnosis

Anorexia in Patients with AIDS

Approval Length

3 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to Megace (megestrol)

AND

4 - One of the following:

4.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

4.2 Patient is unable to swallow capsules

Notes

*This product may require prior authorization.

Product Name: Generic dronabinol

Diagnosis Anorexia in Patients with AIDS

Approval Length 3 month(s)

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of anorexia with weight loss in patients with AIDS

AND

2 - Patient is on antiretroviral therapy [8, 9]

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to Megace (megestrol)

3 . Endnotes

- A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT₃ receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

1. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Antiemesis v.1.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf. Accessed March 15, 2021.
2. Marinol prescribing information. Patheon Softgels, Inc. High Point, NC. March 2021.
3. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed August 22, 2016.
4. American Geriatrics Society 2019 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc*. 2019;00:1-21.
5. Pascual Lopez A, Roque i Figuls M, Urrutia Cuchi G, et al. Systematic review of megestrol acetate in the treatment of anorexia-cachexia syndrome. *J Pain Symptom Manage* 2004;27:360-369.
6. Per clinical consult with HIV specialist, February 4, 2013.
7. Syndros prescribing information. Insys Therapeutics, Inc. Chandler, AZ. December 2019.
8. Williams B, Waters D, Parker K. Evaluation and Treatment of Weight Loss in Adults with HIV Disease. *Am Fam Physician*. 1999;60(3):843-854.
9. Grinspoon S, Mulligan K; Department of Health and Human Services Working Group on the Prevention and Treatment of Wasting and Weight Loss. Weight loss and wasting in

patients infected with human immunodeficiency virus. Clin Infect Dis. 2003;36(Suppl 2):S69-78.

Prior Authorization Guideline

Guideline Name	Caprelsa (vandetanib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none">• Metastatic medullary thyroid cancer (MTC)• Unresectable locally advanced MTC <p style="text-align: center;">AND</p>	

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Endocrinologist

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Caprelsa therapy	

2 . References

1. Caprelsa Prescribing Information. Sanofi Genzyme. Cambridge, MA. December 2016.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. v1.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed on June 28, 2018.

Carbaglu (carglumic acid)

Prior Authorization Guideline

Guideline Name	Carbaglu (carglumic acid)
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Carbaglu (carglumic acid) tablets for oral suspension
Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency Indicated in pediatric and adult patients as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to NAGS deficiency.
Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency Indicated in pediatric and adult patients as maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency.
Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA) Indicated in pediatric and adult patients as adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).

2 . Criteria

Product Name: Brand Carbaglu, Generic carglumic acid
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Diagnosis	Acute Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency

AND

2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g., protein restriction, ammonia scavengers, dialysis)

AND

3 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders

AND

4 - Both of the following (applies to BRAND Carbaglu only):

4.1 Trial and failure or intolerance to generic carglumic acid

AND

4.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Acute Hyperammonemia due to Propionic Acidemia (PA) or Methylmalonic Acidemia (MMA)
Approval Length	1 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA)</p> <p style="text-align: center;">AND</p> <p>2 - Medication will be used as adjunctive therapy to other ammonia lowering therapies (e.g. intravenous glucose, insulin, protein restriction, dialysis)</p> <p style="text-align: center;">AND</p> <p>3 - Patient's plasma ammonia level is greater than or equal to 50 micromol/L</p> <p style="text-align: center;">AND</p> <p>4 - Medication will be used for a maximum duration of 7 days</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders</p>	

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency</p> <p style="text-align: center;">AND</p> <p>2 - NAGS deficiency has been confirmed by genetic/mutational analysis</p> <p style="text-align: center;">AND</p> <p>3 - Medication will be used as maintenance therapy</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a specialist focused in the treatment of metabolic disorders</p> <p style="text-align: center;">AND</p> <p>5 - Both of the following (applies to BRAND Carbaglu only):</p> <p style="padding-left: 20px;">5.1 Trial and failure or intolerance to generic carglumic acid</p> <p style="text-align: center;">AND</p> <p style="padding-left: 20px;">5.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	

Product Name: Brand Carbaglu, Generic carglumic acid	
Diagnosis	Chronic Hyperammonemia due to N-acetylglutamate Synthase (NAGS) Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., plasma ammonia level within the normal range)</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following (applies to BRAND Carbaglu only):</p> <p style="padding-left: 20px;">2.1 Trial and failure or intolerance to generic carglumic acid</p> <p style="text-align: center;">AND</p> <p style="padding-left: 20px;">2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	

3 . References

1. Carbaglu tablet, for suspension. Recordati Rare Diseases Inc , Lebanon, NJ, September 2021.
2. Kenneson, A., Singh, R.H. Presentation and management of N-acetylglutamate synthase deficiency: a review of the literature. Orphanet J Rare Dis 15, 279 (2020).
3. Baumgartner MR, Hörster F, Dionisi-Vici C, et al. Proposed guidelines for the diagnosis and management of methylmalonic and propionic acidemia. Orphanet J Rare Dis. 2014;9:130.

Cayston (aztreonam for inhalation solution)

Prior Authorization Guideline

Guideline Name	Cayston (aztreonam for inhalation solution)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Cayston	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of cystic fibrosis AND 2 - Patient has evidence of Pseudomonas aeruginosa in the lungs	

AND

3 - Patient is seven years of age or older

Product Name: Cayston

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of cystic fibrosis

AND

2 - Patient has evidence of *Pseudomonas aeruginosa* in the lungs

AND

3 - Patient is seven years of age or older

AND

4 - Patient is benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

2 . References

1. Cayston Prescribing Information. Gilead Sciences, Inc., May 2014.
2. Retsch-Bogart GZ, Quittner AL, Gibson RL, et al. Efficacy and safety of inhaled aztreonam lysine for airway *Pseudomonas* in cystic fibrosis. *Chest*. 2009;135:1223-32.

3. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic Fibrosis Foundation Pulmonary Guideline. Pharmacologic approaches to prevention and eradication of initial *Pseudomonas aeruginosa* infection. *Ann Am Thorac Soc*. 2014;11(10):1640-50.

Cequa (cyclosporine 0.09%)

Prior Authorization Guideline

Guideline Name	Cequa (cyclosporine 0.09%)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Cequa (cyclosporine 0.09%) ophthalmic solution
Keratoconjunctivitis sicca Indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye).

2 . Criteria

Product Name: Cequa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of keratoconjunctivitis sicca (dry eye)	

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- Restasis (cyclosporine 0.05%)
- Xiidra (lifitegrast)

Product Name: Cequa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to Cequa therapy (e.g., increased tear production or improvement in dry eye symptoms).	

3 . Endnotes

- A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Anti-inflammatory therapies (topical cyclosporine and corticosteroids), systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

1. Cequa Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. September 2019.
2. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. November 2018. <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed March 25, 2020.

Prior Authorization Guideline

Guideline Name	CGRP Inhibitors - PA, NF
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Episodic Cluster Headache Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant sulfate)
Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.
Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.
Drug Name: Qulipta (atogepant)

Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.

Drug Name: Ubrelvy (ubrogepant)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

Drug Name: Zavzpret (zavegepant) nasal spray

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Zavzpret is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Aimovig or Emgality 120 mg/mL

Diagnosis	Preventive Treatment of Migraine
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)
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Product Name: Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Both of the following:	

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)

- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Emgality

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Aimovig, Ajovy, or Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">AND</p> <p>2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy</p> <p style="text-align: center;">AND</p> <p>3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]</p> <p style="text-align: center;">AND</p> <p>4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines</p>	

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [25]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure ((after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.
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Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of episodic migraines</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [27]</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Diagnosis of chronic migraines</p> <p style="text-align: center;">AND</p> <p>1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]</p> <p style="text-align: center;">AND</p> <p>1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older [I]</p>	

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity	
AND	
2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy	
AND	

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity	
AND	
2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy	
AND	
3 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines	
Notes	Nurtec ODT: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 months.

Product Name: Emgality 100 mg/mL

Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of episodic cluster headache</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [20]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [1]</p> <p style="text-align: center;">AND</p> <p>4 - Medication will not be used in combination with another injectable CGRP inhibitor</p>	

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p>	

AND

2 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of migraine with or without aura</p> <p style="text-align: center;">AND</p> <p>2 - Will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [I]</p> <p style="text-align: center;">AND</p> <p>4 - One of the following: [23]</p> <ul style="list-style-type: none">• Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)• Contraindication to all triptans <p style="text-align: center;">AND</p>	

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 23]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines</p>	

Product Name: Ubrovelvy	
Diagnosis	Acute Treatment of Migraine

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [23]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 23]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines</p>	

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [23]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Trial and failure, or intolerance to one of the following:

- Ubrelvy
- Nurtec ODT

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 23]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

7 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Will not be used for preventive treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines</p>	

Product Name: Ajovy	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]

Guideline Type	Non Formulary
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Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming two of the following [D, E, F, G, 10]:

3.1 One of the following:

- History of failure (after at least a two month trial) or intolerance to Elavil (amitriptyline) or Effexor (venlafaxine)
- Patient has a contraindication to both Elavil (amitriptyline) and Effexor (venlafaxine)

OR

3.2 One of the following:

- History of failure (after at least a two month trial) or intolerance to Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- Patient has a contraindication to both Depakote/Depakote ER (divalproex sodium) and Topamax (topiramate)

OR

3.3 One of the following:

- History of failure (after at least a two month trial) or intolerance to one of the following beta blockers: atenolol, propranolol, nadolol, timolol, or metoprolol
- Patient has a contraindication to all of the following beta blockers: atenolol, propranolol, nadolol, timolol, metoprolol

OR

3.4 One of the following:

- History of failure (after at least a two month trial) or intolerance to Atacand (candesartan)
- Patient has a contraindication to Atacand (candesartan)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to both of the following:

- Aimovig
- Emgality

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

3 . Endnotes

- A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
- B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
- C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
- D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 23].
- E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
- F. The OptumRx clinical team consulted with a neurologist on the prospective review of the CGRP Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more

on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).

- G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].
- H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
- I. The safety and effectiveness in pediatric patients has not been established [1, 17-18, 19, 21, 28].
- J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [24]

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Chenodal (chenodiol)

Prior Authorization Guideline

Guideline Name	Chenodal (chenodiol)
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Chenodal (chenodiol)
Radiolucent Gallstones Indicated for patients with radiolucent stones in well-opacifying gallbladders, in whom selective surgery would be undertaken except for the presence of increased surgical risk due to systemic disease or age. The likelihood of successful dissolution is far greater if the stones are floatable or small. For patients with nonfloatable stones, dissolution is less likely and added weight should be given to the risk that more emergent surgery might result from a delay due to unsuccessful treatment. Safety of use beyond 24 months is not established. Chenodiol will not dissolve calcified (radiopaque) or radiolucent bile pigment stones.

2 . Criteria

Product Name: Chenodal	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of radiolucent gallstones

AND

2 - Patient has a well-opacifying gallbladder visualized by oral cholecystography

AND

3 - Trial and failure, contraindication or intolerance to ursodiol

AND

4 - Patient is not a candidate for surgery

AND

5 - Stones are not calcified (radiopaque) or radiolucent bile pigment stones

AND

6 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- A provider who has specialized expertise in the management of gallstones

Product Name: Chenodal	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment as evidenced by oral cholecystograms or ultrasonograms

AND

2 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- A provider who has specialized expertise in the management of gallstones

3 . References

1. Chenodal Prescribing Information. Retrophin, Inc. San Diego, CA. November 2021.

Cholbam (cholic acid)

Prior Authorization Guideline

Guideline Name	Cholbam (cholic acid)
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Cholbam (cholic acid)
<p>Bile acid synthesis disorders due to single enzyme defects (SEDs) Indicated for the treatment of bile acid synthesis disorders due to single enzyme defects (SEDs). Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or peroxisomal disorders (PDs) including Zellweger spectrum disorders have not been established.</p> <p>Adjunctive treatment for peroxisomal disorders (PDs) Indicated for adjunctive treatment of peroxisomal disorders (PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat-soluble vitamin absorption. Limitation of use: The safety and effectiveness of Cholbam on extrahepatic manifestations of bile acid synthesis disorders due to SEDs or PDs including Zellweger spectrum disorders have not been established.</p>

2 . Criteria

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders

Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: [1-6,8,A,B]</p> <ul style="list-style-type: none"> • An abnormal urinary bile acid analysis by mass spectrometry • Molecular genetic testing consistent with the diagnosis <p style="text-align: center;">AND</p> <p>2 - Prescribed by one of the following: [2,7,E]</p> <ul style="list-style-type: none"> • Hepatologist • Medical geneticist • Pediatric gastroenterologist • Other specialist that treats inborn errors of metabolism 	

Product Name: Cholbam	
Diagnosis	Peroxisomal disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a peroxisomal disorder based on one of the following: [2-5,8,C,D]</p> <ul style="list-style-type: none"> • An abnormal urinary bile acid analysis by mass spectrometry • Molecular genetic testing consistent with the diagnosis <p style="text-align: center;">AND</p>	

2 - Patient exhibits manifestations of at least one of the following: [2-3]

- Liver disease (e.g., jaundice, elevated serum transaminases)
- Steatorrhea
- Complications from decreased fat-soluble vitamin absorption (e.g., poor growth)

AND

3 - Prescribed by one of the following: [2,7,E]

- Hepatologist
- Medical geneticist
- Pediatric gastroenterologist
- Other specialist that treats inborn errors of metabolism

AND

4 - Used as adjunctive treatment [2-3]

Product Name: Cholbam	
Diagnosis	Bile acid synthesis disorders or Peroxisomal disorders
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by improvement in liver function (e.g., aspartate aminotransferase [AST], alanine aminotransferase [ALT])	

3 . Endnotes

- A. Congenital deficiencies in the enzymes responsible for catalyzing key reactions in the synthesis of primary bile acids cholic acid and chenodeoxycholic acid are referred to as bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1] 3 beta-hydroxy-D5-C27-steroid oxidoreductase deficiency (3 beta-HSD) and D4-3-oxosteroid 5

- beta-reductase deficiency (AKR1D1 or D4-3-oxo-R), inherited by an autosomal recessive mode, are the most frequent inborn errors of primary bile acid synthesis causing early cirrhosis and liver failure. [6] See Background Table 1 for a list of known bile acid synthesis disorders (BASDs) due to single enzyme defects (SEDs). [1]
- B. 2- (or alpha-) methylacyl-CoA racemase (AMACR) deficiency is a deficiency of a single peroxisomal enzyme that may manifest secondary abnormalities of bile acid synthesis; it may thus technically be considered a BASD, as well as, a peroxisomal disorder (PD). [2-5]
 - C. The spectrum of diseases referred to as peroxisomal disorders (PDs) involve defects in later steps of the bile acid synthetic pathway, such as impaired side-chain oxidation; [3] PDs are therefore classified as either disorders of peroxisome biogenesis (eg, Zellweger syndrome) or deficiencies of a single peroxisomal enzyme (eg, 2- (or alpha-)methylacyl-CoA racemase [AMACR] deficiency). [3] See Background Table 2 for a list of known PDs. [5]
 - D. Zellweger syndrome, infantile Refsum disease, neonatal adrenoleukodystrophy and rhizomelic chondrodysplasia punctata type 1 (RCDP1) are examples of defective biogenesis in which peroxisomes are absent. [4-5] The first 3 disorders are thought to represent a clinical continuum, referred to as Zellweger spectrum disorders (ZSD), with Zellweger syndrome the most severe, infantile Refsum disease the mildest, and neonatal adrenoleukodystrophy intermediate in severity. [5]
 - E. As per the prescribing information [2], treatment with Cholbam should be initiated and monitored by an experienced hepatologist or pediatric gastroenterologist. At the University of California, San Francisco, medical geneticists see patients with PDs, while specialists in pediatric gastroenterology see patients with BASDs. [7]
 - F. Cholbam should be discontinued if liver function does not improve within 3 months of starting treatment. [2] An additional month is added to the initial authorization duration to allow for patient follow-up with the provider.

4 . References

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Cibinqo (abrocitinib)

Prior Authorization Guideline

Guideline Name	Cibinqo (abrocitinib)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Cibinqo (abrocitinib)
Atopic Dermatitis Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Limitations of Use: Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2 . Criteria

Product Name: Cibinqo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe atopic dermatitis

AND

2 - One of the following:

- Involvement of at least 10% body surface area (BSA)
- SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A]

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

AND

7 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Cibinqo may be used with concomitant topical or inhaled corticosteroids
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Product Name: Cibinqo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:	
<ul style="list-style-type: none">• Reduction in body surface area involvement from baseline• Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A]	
AND	
2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*	
Notes	*Cibinqo may be used with concomitant topical or inhaled corticosteroids

3 . Background

Clinical Practice Guidelines			
Table 1. Relative potencies of topical corticosteroids [2]			
Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05

	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream	0.1
	Triamcinolone acetonide	Cream, ointment	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

- A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [3, 4] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score ($A/5 + 7B/2 + C$) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [5]

5 . References

1. Cibinqo Prescribing Information. Pfizer Labs. New York, NY. February 2023.
2. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023; Epub ahead of print.
3. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. *Dermatology*. 1993; 186:23-31.
4. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet* 2017; 389(10086)(suppl):2287-2303.
5. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. *Curr Probl Dermatol*. 2011; 41:149-55.

Cimzia (certolizumab pegol)

Prior Authorization Guideline

Guideline Name	Cimzia (certolizumab pegol)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Cimzia (certolizumab pegol)
<p>Crohn's Disease Indicated for reducing signs and symptoms of Crohn's disease (CD) and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.</p>
<p>Rheumatoid Arthritis Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis.</p>
<p>Psoriatic Arthritis Indicated for the treatment of adult patients with active psoriatic arthritis (PsA).</p>
<p>Ankylosing Spondylitis Indicated for the treatment of adults with active ankylosing spondylitis.</p>
<p>Plaque Psoriasis Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy.</p>
<p>Non-radiographic Axial Spondyloarthritis Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.</p>

2 . Criteria

Product Name: Cimzia	
Diagnosis	Crohn's disease
Approval Length	16 Weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active Crohn's disease</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2]:</p> <ul style="list-style-type: none"> • 6-mercaptopurine (Purinethol) • Azathioprine (Imuran) • Corticosteroids (e.g., prednisone, methylprednisolone) • Methotrexate (Rheumatrex, Trexall) <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a gastroenterologist</p>	

Product Name: Cimzia	
Diagnosis	Crohn's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of positive clinical response to therapy

Product Name: Cimzia

Diagnosis Rheumatoid Arthritis (RA)

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication or intolerance to one non-biologic DMARD [e.g., Rheumatrex/Trexall (methotrexate), Arava (leflunomide), Azulfidine (sulfasalazine)] [3]

Product Name: Cimzia

Diagnosis Rheumatoid Arthritis (RA)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis [1, 4]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Rheumatologist 	

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to two NSAIDs [5]

Product Name: Cimzia

Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Cimzia

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis [1, 6]

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Cimzia	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:	
<ul style="list-style-type: none">• Reduction the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of active non-radiographic axial spondyloarthritis	
AND	
2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the	

upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 5]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Trial and failure, contraindication, or intolerance to two NSAIDs [5]

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

- A. The recommended initial adult dose of Cimzia is 400 mg (given as two subcutaneous injections of 200 mg) initially, and at Weeks 2 and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks.

4 . References

1. Cimzia Prescribing Information. UCB. Smyrna, GA. September 2019.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2018;113:481-517.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.

4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
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6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol* 2019;80:1029-72.

Cinqair (reslizumab)

Prior Authorization Guideline

Guideline Name	Cinqair (reslizumab)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Cinqair (reslizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype. Limitation of Use: Cinqair is not indicated for treatment of other eosinophilic conditions; Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Cinqair	
Approval Length	6 Months [H]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of severe asthma [1]

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [1, B, D]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [A]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [C, E, F]

- High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day]
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 18 years

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/immunologist

Product Name: Cinqair	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)</p> <p>AND</p> <p>2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications</p> <p>AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Pulmonologist• Allergist/Immunologist	

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	200		400
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

This is not a table of equivalence, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply

potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

- A. In two duplicate 52-week Phase III studies, eligible patients were required to have experienced at least one asthma exacerbation that required a systemic corticosteroid for at least 3 days within the past 12 months. [2, 3]
- B. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [8]
- C. The ERS/ATS guidelines define severe asthma as that which requires treatment with high-dose ICSs plus a second controller (or systemic corticosteroids [CSs]) to prevent progression to uncontrolled disease status or continuing uncontrolled disease status despite this therapy. [4]
- D. Recommended per national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
- E. In the pivotal study for Nucala (mepolizumab), another IL-5 antagonist indicated for severe eosinophilic asthma, patients met the inclusion criteria with a well-documented requirement for regular treatment with high dose ICS (i.e., greater than or equal to 880 mcg/day fluticasone propionate or equivalent daily), with or without maintenance oral corticosteroids, in the 12 months prior to Visit 1. [5]
- F. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
- G. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].
- H. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]

5 . References

1. Cinqair Prescribing Information. Teva Respiratory, LLC. Frazer, PA. June 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, doubleblind, randomised, placebo-controlled, phase 3 trials. *Lancet Respir Med*. 2015;3(5):355-366.
3. Bjermer L, Lemiere C, Maspero J, et al. A randomized phase 3 study of the efficacy and safety of reslizumab in subjects with asthma with elevated eosinophils. *Eur Respir J*. 2014;44(Suppl 58):P299. Paper presented at: European Respiratory Society International Congress; September 6-10, 2014; Munich, Germany.
4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014; 43:343-373.
5. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. *Lancet*. 2012; 380: 651-59.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2021 update). 2021 www.ginasthma.org. Accessed April 15, 2022.
7. Per clinical consult with allergist specialist. May 4, 2016.
8. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.

Prior Authorization Guideline

Guideline Name	CNS Stimulants QL Override
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Guideline Note:

Effective Date:	6/15/2022
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1 . Criteria

Product Name: Adderall, Adderall XR, Adhansia XR, Aptensio XR, brand methylphenidate XR, Adzenys ER, Adzenys XR-ODT, brand Amphetamine ER, Azstarys, Concerta, Cotempla XR-ODT, Daytrana, Desoxyn, Dyanavel XR, Evekeo, Evekeo ODT, Focalin, Focalin XR, Jornay PM, Metadate CD, Metadate ER, generic methylphenidate chewable tablets, Methylin oral solution, Mydayis, Procentra, Quillichew ER, Quillivant XR, Relexxii, Ritalin, Ritalin LA, Vyvanse, brand Zenzedi, generic dextroamphetamine	
Diagnosis	ADHD overrides for quantities below the FDA max dose
Approval Length	12 Months (except for dose titration)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Quantity limit overrides will be granted for one of the following:</p> <p> 1.1 Dose titration purposes (one time authorization)</p>	

OR

1.2 Requested strength/dose is commercially unavailable

OR

1.3 Patient is on a dose alternating schedule

OR

1.4 Prescribed by or in consultation with a provider with expertise in the treatment of ADD or ADHD

Notes	QL override program applies to both the brand and generic (if available) of the listed products.
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Product Name: Adderall, Adderall XR, Adhansia XR, Aptensio XR, brand methylphenidate XR, Adzenys ER, Adzenys XR-ODT, brand Amphetamine ER, Azstarys, Concerta, Cotempla XR-ODT, Daytrana, Desoxyn, Dyanavel XR, Evekeo, Evekeo ODT, Focalin, Focalin XR, Jornay PM, Metadate CD, Metadate ER, generic methylphenidate chewable tablets, Methylin oral solution, Mydayis, Procentra, Quillichew ER, Quillivant XR, Relexxii, Ritalin, Ritalin LA, Vyvanse, brand Zenzedi, generic dextroamphetamine

Diagnosis	ADHD QL overrides for quantities that exceed the FDA max dose
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Overrides will be granted for quantities that exceed the FDA maximum daily dose when submission of peer-reviewed medical literature or national compendia supporting the use of higher doses is provided

Notes	QL override program applies to both the brand and generic (if available) of the listed products.
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2 . Background

Clinical Practice Guidelines			
Table 1:			
Generic Name	Brand Name	Available Strengths	Maximum daily dose
amphetamine/ dextroamphetamine	ADDERALL	5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg, 20 mg, 30 mg	60 mg/day
amphetamine/ dextroamphetamine extended-release	ADDERALL XR	5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg	30 mg/day
amphetamine/ dextroamphetamine extended-release	MYDAYIS	12.5 mg, 25 mg, 37.5 mg, 50 mg	50 mg/day
amphetamine extended-release, orally disintegrating tablet	ADZENYS XR-ODT	3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg, 18.8 mg	12.5 mg (\geq 13 years old) 18.8 mg (6-12 years old)
amphetamine extended-release, suspension	ADZENYS ER	1.25 mg amphetamine per mL	Pediatric patients (ages 6 to 12 years): 18.8 mg (15 mL) Pediatric patients (ages 13 to 17 years): 12.5 mg (10 mL)

			Adults: 12.5 mg (10 mL)
amphetamine extended-release, suspension	DYANAVEL XR	2.5 mg/ml	20 mg/day
amphetamine	EVEKEO	5 mg, 10 mg	60 mg/day
amphetamine, orally disintegrating tablet	EVEKEO ODT	5 mg, 10 mg, 15 mg, 20 mg	60 mg/day
dexmethylphenidate	FOCALIN	2.5 mg, 5 mg, 10 mg	20 mg/day
dexmethylphenidate extended-release	FOCALIN XR	5 mg, 10 mg, 15 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg	40 mg/day
dextroamphetamine	DEXEDRINE	5 mg, 10 mg, 15 mg	60 mg/day
dextroamphetamine solution	PROCENTRA	5 mg/5ml	60 mg/day
dextroamphetamine	ZENZEDI	2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg	60 mg/day
lisdexamfetamine	VYVANSE	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg	70 mg/day
methamphetamine	DESOXYN	5 mg	25 mg
methylphenidate extended release OSM	CONCERTA	18 mg, 27 mg, 36 mg, 54 mg	72 mg/day
methylphenidate extended release OSM	RELEXXII	72mg	72 mg/day
methylphenidate extended-release,	COTEMPLA XR ODT	8.6 mg, 17.3 mg, 25.9 mg	51.8 mg/day

orally disintegrating tablet			
methylphenidate transdermal	DAYTRANA PATCHES	10 mg/9hr, 15 mg/9hr, 20 mg/9hr, 30 mg/9hr	30 mg/9 hr
methylphenidate extended-release	JORNAY PM	20 mg, 40 mg, 60 mg, 80 mg, 100 mg	100 mg/day
methylphenidate extended-release	ADHANSIA XR	25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg	100 mg/day
methylphenidate extended-release	APTENSIO XR	10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg	60 mg/day
methylphenidate extended-release	METADATE CD	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg	60 mg/day
methylphenidate, chewable tablet	METHYLIN CHEW TAB	2.5 mg, 5 mg, 10 mg	60 mg/day
methylphenidate extended-release	METHYLPHENIDATE ER	10 mg	60 mg/day
methylphenidate extended-release, chewable tablet	QUILLICHEW ER	20 mg, 30 mg, 40 mg	60 mg/day
methylphenidate extended-release, suspension	QUILLIVANT XR	300 mg/60 mL, 500 mg/120 mL, 750 mg/150 mL, 900 mg/180 mL	60 mg/day
methylphenidate extended-release	RITALIN LA	10 mg, 20 mg, 30 mg, 40 mg, 60 mg	60 mg/day

methylphenidate extended-release	RITALIN SR/ METADATE ER/ METHYLIN ER	20 mg	60 mg/day
methylphenidate	RITALIN / METHYLIN	5 mg, 10 mg, 20 mg	60 mg/day
serdexmethylphenidate and dexamethylphenidate	AZSTARYS	26.1 mg/5.2 mg, 39.2 mg/7.8 mg, 52.3 mg/10.4 mg	52.3 mg/10.4 mg once daily.

3 . References

1. Adderall Prescribing Information. Teva Pharmaceuticals. Horsham, PA. April 2020.
2. Adderall XR Prescribing Information. Shire US Inc. Lexington, MA. December 2020.
3. Concerta Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. July 2021.
4. Dexedrine Spansules Prescribing Information. Amedra Pharmaceuticals. Horsham, PA. June 2019.
5. Desoxyn Prescribing Information. Recordati Rare Diseases, Inc. Lebanon, NJ. April 2019.
6. Focalin XR Prescribing Information. Novartis Pharmaceuticals Corp. East Hanover, NJ. June 2021.
7. Metadate CD Prescribing Information. UCB, Inc. Smyrna, GA. October 2016.
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Prior Authorization Guideline

Guideline Name	Colony-Stimulating Factors (CSFs)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for

the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human immunodeficiency virus (HIV)-related neutropenia Has been prescribed for HIV-related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs

associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-

induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Drug Name: Releuko (filgrastim-ayow)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-

cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Off Label Uses: Patients Undergoing Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Has been used to increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Hepatitis-C Interferon Induced Neutropenia Has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24, M]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11, 37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Rolvedon (eflapegrastim-xnst)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Rolvedon is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Drug Name: Udenyca (pegfilgrastim-cbqv, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Udenyca is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

2 . Criteria

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT</p> <p style="text-align: center;">OR</p> <p>1.2 For mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</p> <p style="text-align: center;">OR</p> <p>1.3 For peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p>	

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, Releuko only)

Product Name: Leukine

Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
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Approval Length	3 months or duration of therapy [C]
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

3 - Patient is 55 years of age or older [3, B]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Neupogen, Nivestym, Releuko, or Zarxio

Diagnosis	AML Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of acute myeloid leukemia (AML) [A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient has completed induction or consolidation chemotherapy [27]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a hematologist/oncologist</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Zarxio</p>	

Product Name: Fulphila, Fylnetra, Granix, Leukine (off-label), Neulasta/Neulasta Onpro, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization, Non Formulary
<p>Approval Criteria</p> <p>1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:</p> <p>1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense</p>	

chemotherapy protocol for primary breast cancer (see Table 2 in Background section) [16-19, 34, D, E]

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient receiving chemotherapy regimens associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient receiving chemotherapy regimen associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 One or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 2 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34, K]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, Releuko, and Granix only)

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary
Approval Criteria	
1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:	
1.1 Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]	

OR

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca, Zarxio, or Ziextenzo

Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, I]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patients with FN at high risk for infection-associated complications [16, 17, 34]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g. chart notes) confirming trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, Releuko, and Granix only)

OR

5.2 Paid claims or submission of medical records (e.g. chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Leukine, Neulasta/Neulasta Onpro, Neupogen, Nivestym (Off-Label), Nyvepria (Off-Label), Releuko (Off-Label), Stimufend (Off-label), Udenyca, Zarxio (Off-Label), or Ziextenzo (Off-Label)

Diagnosis	Acute Radiation Syndrome (ARS)
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Approval Length	1 Month [N]
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient was/will be acutely exposed to myelosuppressive doses of radiation

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, and Releuko only)

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend and Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - For patients with SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC less than or equal to 500 cells/mm ³) [16]	
AND	
2 - Prescribed by or in consultation with a hematologist/oncologist	
AND	
3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, and Releuko)	

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human immunodeficiency virus (HIV)-Related Neutropenia (Off-label)
Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is infected with HIV virus [11- 13]</p> <p style="text-align: center;">AND</p> <p>2 - ANC less than or equal to 1,000 (cells/mm³) [12, 13]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist/oncologist • Infectious disease specialist <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, and Releuko only)</p>	

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - One of the following:

1.1 All of the following:

1.1.1 Patients infected with Hepatitis C virus

AND

1.1.2 Patient is undergoing treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.1.3 Neutropenia (ANC less than or equal to 500 cells/mm³) after dose reduction of Peg-Intron or Pegasys [F]

OR

1.2 Both of the following:

1.2.1 Patients who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm³) due to treatment with Peg-Intron (peginterferon alfa-2b) or Pegasys (peginterferon alfa-2a)

AND

1.2.2 One of the following: [G]

1.2.2.1 Patient with HIV co-infection

OR

1.2.2.2 Status post liver transplant

OR

1.2.2.3 Patient with established cirrhosis

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Infectious disease specialist
- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to Zarxio (applies to Neupogen, Nivestym, and Releuko only)

3 . Background

Benefit/Coverage/Program Information

Table 1. Intergroup C9741 Protocol [19]

Regimen	Drugs	G-CSF
Sequential	Doxorubicin q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles, then cyclophosphamide q2 weeks x 4cycles	Days 3 to 10 of each cycle
Concurrent	Doxorubicin + cyclophosphamide q2 weeks x4 cycles, then paclitaxel q2 weeks x4 cycles	Days 3 to 10 of each cycle

Table 2. Examples of chemotherapy regimens with a high risk of FN (> 20%) [16]

Cancer	Regimen
Bladder Cancer	<ul style="list-style-type: none"> • Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	<ul style="list-style-type: none"> • VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer ¹⁸	<ul style="list-style-type: none"> • Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	<ul style="list-style-type: none"> • FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	<ul style="list-style-type: none"> • TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	<ul style="list-style-type: none"> • Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	<ul style="list-style-type: none"> • Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	<ul style="list-style-type: none"> • Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	<ul style="list-style-type: none"> • Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma	<ul style="list-style-type: none"> • DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)

Ovarian Cancer	<ul style="list-style-type: none"> • Topotecan • Docetaxel
Pancreatic Cancer	<ul style="list-style-type: none"> • FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	<ul style="list-style-type: none"> • MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	<ul style="list-style-type: none"> • Topotecan
Testicular Cancer	<ul style="list-style-type: none"> • VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	Regimen
Occult Primary-Adenocarcinoma	<ul style="list-style-type: none"> • Gemcitabine/docetaxel
Breast Cancer	<ul style="list-style-type: none"> • Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	<ul style="list-style-type: none"> • Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	<ul style="list-style-type: none"> • FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL) ²⁶	<ul style="list-style-type: none"> • GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubivin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin • Bendamustine
Non-Small Cell Lung Cancer	<ul style="list-style-type: none"> • Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel • Cisplatin/etoposide

	<ul style="list-style-type: none"> • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	<ul style="list-style-type: none"> • Carboplatin/docetaxel
Prostate Cancer	<ul style="list-style-type: none"> • Cabazitaxel
Testicular Cancer	<ul style="list-style-type: none"> • Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	<ul style="list-style-type: none"> • Irinotecan/cisplatin • Epirubicin/cisplatin/5-fluorouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	<ul style="list-style-type: none"> • Etoposide/carboplatin
Uterine Cancer	<ul style="list-style-type: none"> • Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	Brand Name
Busulfan	Busulfex [®] , Myleran [®]
Carboplatin	Paraplatin [®]
Carmustine (BCNU)	BiCNU [®] , Gliadel [®]
Chlorambucil	Leukeran [®]
Cladribine	Luestatin [®]
Cyclophosphamide	Cytoxan [®]
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome [®]
Dactinomycin	Actinomycin D [®] , Cosmegen [®]
Daunorubicin	Cerubidine [®]
Daunorubicin Liposomal	DaunoXome [®]
Doxorubicin	Adriamycin PFS [®] , Adriamycin RDF [®] , Adriamycin [®]
Doxorubicin Liposomal	Doxil [®]
Etoposide	Etopophos [®] , Toposar [®] , VePesid [®]
Fluorouracil (5-FU)	Adrucil [®] , Efudex [®] , Fluoroplex [®]
Floxuridine	FUDR [®]
Fludarabine	Fludara [®]
Hydroxyurea	Droxia [®] , Hydrea [®]
Ifosfamide/Mesna	Ifex [®] , Mesnex [®]
Lomustine (CCNU)	CeeNU [®]
Mechlorethamine (Nitrogen Mustard)	Mustargen [®]
Melphalan	Alkeran [®]
Mercaptopurine (6-MP)	Purinethol [®]
Methotrexate	Rheumatrex [®] , Trexall [®]
Mitomycin	N/A

Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A
Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

- A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
- B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
- C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
- D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
- E. Per hematology/oncology consultant and member of P&T in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
- F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm³. [21, 22]
- G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm³) due to treatment with Peg-Intron or Pegasys.
- H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]

- I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
- J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
- K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm³) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]
- L. Note: This list is NOT all inclusive: See Table 4 in Background section
- M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbofilgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
- N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10⁹ cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

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Cometriq (cabozantinib)

Prior Authorization Guideline

Guideline Name	Cometriq (cabozantinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of one of the following: [1,2] <ul style="list-style-type: none">• Metastatic medullary thyroid cancer (MTC)• Unresectable locally advanced MTC <p style="text-align: center;">AND</p>	

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hematologist
- Endocrinologist

Product Name: Cometriq	
Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Cometriq therapy	

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer (NSCLC) [3]	

AND

2 - Positive for RET gene rearrangements [3]

AND

3 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Cometriq	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC) (off-label)
Approval Length	11 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Cometriq therapy	

2 . Endnotes

- A. In a phase 3 clinical trial of 330 patients, a statistically significant prolongation in progression free survival (PFS) was demonstrated among Cometriq-treated patients compared to those receiving placebo, with a median PFS time of 11.2 months and 4 months in the Cometriq and placebo arms, respectively. [1]

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Prior Authorization Guideline

Guideline Name	Compounded Drugs
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative
Approval Criteria 1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated AND 2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery	

AND

3 - If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. *Approved national compendia are referenced in the "Coverage of Off-Label or Non-FDA Approved Indications" Guideline **Administrative guideline may not apply to all compound reviews, depending on the ingredients being used and client elections.
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Product Name: Diclofenac compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include diclofenac will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Diagnosis of one of the following:</p> <ul style="list-style-type: none">• Osteoarthritis	

- Rheumatoid arthritis
- Mild to moderate pain
- Pain due to minor strains, sprains or contusions
- Migraine
- Primary dysmenorrhea
- Actinic keratosis
- Ankylosing spondylitis
- Inflammatory disorder of the eye
- Photophobia
- Pain in the eye

AND

1.3 The final dosage form will be for oral, topical, or ophthalmic use

AND

1.4 The final dosage form and strength of the diclofenac ingredient is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply.</p>
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Product Name: Flurbiprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Compounded drugs that include flurbiprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Intraoperative miosis inhibition

AND

1.3 The final dosage form will be for oral or ophthalmic use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply.
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Product Name: Fluticasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include fluticasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 3 months of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply.
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Product Name: Gabapentin compounds**

Approval Length | 6 months, unless the provider requests for a shorter length of therapy

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include gabapentin will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 3 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Patient must have one of the following diagnoses:</p> <ul style="list-style-type: none"> • Partial seizures • Postherpetic neuralgia • Restless leg syndrome (RLS) <p style="text-align: center;">AND</p> <p>1.3 The final dosage form will be for oral use</p> <p style="text-align: center;">AND</p> <p>1.4 The requested dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).</p>	
Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply.</p>

Product Name: Ketamine compounds**

Approval Length	6 months, unless the provider requests for a shorter length of therapy
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Compounded drugs that include ketamine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 16 years of age or older

AND

1.2 One of the following:

1.2.1 Patient is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation

OR

1.2.2 Patient is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents

OR

1.2.3 Patient is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide

AND

1.3 The final dosage form will be for injection

AND

1.4 The requested dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.6 The requested dose does not exceed the concentration limit of 100mg/mL*

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. *According to the prescribing information, 100mg/ml product must be diluted prior to administration. **Administrative guideline and other drug-specific guidelines may apply.
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Product Name: Ketoprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include ketoprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Diagnosis of one of the following:</p> <ul style="list-style-type: none">• Osteoarthritis• Rheumatoid arthritis• Acute pain	

- Primary dysmenorrhea

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes

Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.

**Administrative guideline and other drug-specific guidelines may apply.

Product Name: Levocetirizine compounds**

Approval Length

6 months, unless the provider requests for a shorter length of therapy

Guideline Type

Prior Authorization

Approval Criteria

1 - Compounded drugs that include levocetirizine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 6 months of age or older

AND

1.2 Diagnosis of one of the following:

- Seasonal or perennial allergic rhinitis
- Uncomplicated skin manifestations of chronic idiopathic urticaria

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply.</p>
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Product Name: Mometasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include mometasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 2 years of age or older</p> <p>AND</p>	

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply.</p>
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Product Name: Acyclovir ointment 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include acyclovir ointment 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p>	

AND

1.2 Diagnosis for one of the following:

- Management of initial genital herpes
- Limited non-life-threatening mucutaneous herpes simplex virus infection in immunocompromised patients

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply.
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Product Name: Doxepin cream 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
Approval Criteria 1 - Compounded drugs that include doxepin cream 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met: 1.1 Patient is 18 years of age or older	

AND

1.2 Treatment of moderate pruritus with atopic dermatitis or lichen simplex chronicus

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes

Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.

**Administrative guideline and other drug-specific guidelines may apply.

2 . Background

Benefit/Coverage/Program Information

Table 1: Drugs that were withdrawn from the market due to safety or effectiveness

3,3',4',5-tetrachlorosalicylanilide	Methapyrilene
Adenosine phosphate	Methopholine
Adrenal cortex	Mibefradil dihydrochloride
Azaribine	Nitrofurazone
Benoxaprofen	Nomifensine maleate

Bithionol	Oxyphenisatin
Bromfenac sodium	Oxyphenisatin acetate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Pipamazine
Casein, iodinated	Potassium arsenite
Chlorhexidine gluconate	Potassium chloride
Chlormadinone acetate	Povidone
Chloroform	Reserpine
Cobalt	Sparteine sulfate
Dexfenfluramine hydrochloride	Sulfadimethoxine
Diamthazole dihydrochloride	Sulfathiazole
Dibromsalan	Suprofen
Diethylstilbestrol	Sweet spirits of nitre
Dihydrostreptomycin sulfate	Temafloracin hydrochloride
Dipyron	Terfenadine
Encainide hydrochloride	Tetracycline
Fenfluramine hydrochloride	Ticrynafen
Flosequinan	Tribromsalan
Gelatin	Trichloroethane
Glycerol, iodinated	Urethane
Gonadotropin, chorionic	Vinyl chloride
Mepazine	Zirconium

Metabromsalan	Zomepirac sodium
Methamphetamine hydrochloride	

Diclofenac Compounds

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:

- Management of mild to moderate acute pain or osteoarthritis pain,
- Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
- Relieve acute pain associated with minor sprains, strains, and contusions
- Treatment of primary dysmenorrhea
- Treatment of acute migraine attacks with or without aura in adults
- Treatment of actinic keratosis
- Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.
- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.
- Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation.

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2012; Horizant prescribing information, 2013; Neurontin prescribing information, 2015).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2015).
- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2013).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2016)
- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2016)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2016)

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H1) receptor antagonist, is indicated for:
 - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
 - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
 - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older
- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 12 years of age.

- Mometasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and powder for inhalation.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.

Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate.

3 . Endnotes

- A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
- B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]
- C. Benefit design recommendations provided in the OptumRx Commercial Implementation Guide: (1) \$200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
- D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer's instructions or the product's approved labeling.

4 . References

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2. Application of Federal Law to Practice of Pharmacy Compounding. Available at: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm155666.htm>. Accessed July 22, 2019.
3. Drugs withdrawn or removed from the market for reasons of safety and effectiveness. Available at: http://www.ecfr.gov/cgi-bin/text-idx?SID=19d815f162256955b974e911f8ca0e46&mc=true&node=se21.4.216_124&rgn=div8. Accessed March 5, 2020.
4. DRUGDEX [Internet database]. Greenwood Village, CO: Thomson MICROMEDEX, updated periodically. Accessed October 31, 2018.
5. Flurbiprofen Tablet Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. May 2016.
6. Ocufer Prescribing Information. Allergan. Irvine, CA. July 2012.
7. Gralise prescribing information. Depmed. Neward, CA. December 2012.
8. Horizant prescribing information. Santa Clara, CA. July 2013
9. Neurontin prescribing information. Pfizer. New York, NY. September 2015.
10. Ketalar prescribing information. Par Pharmaceutical Companies. Spring Valley, NY. January 2016.
11. Ketoprofen Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. July 2015.
12. Ketoprofen Extended-Release Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. July 2015.
13. Xyzal Prescribing Information. UCB Pharma. Smyrna, GA. June 2016.
14. Elocon Cream, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. April 2013.
15. Elocon Lotion, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
16. Elocon Ointment, 0.1%. Merck & Co., Inc. Whitehouse Station, NJ. September 2015.
17. Spravato Prescribing Information. Janssen Pharmaceuticals. Titusville, NJ. May 2019.
18. Sinuva Prescribing Information. Intersect ENT, Inc. Menlo Park, CA. December 2017.
19. Zovirax Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. April 2018.
20. Zonalon Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2017.

Prior Authorization Guideline

Guideline Name	Constipation Agents
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Relistor injection	
Approval Length	4 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of opioid-induced constipation AND 2 - One of the following: 2.1 Patient has chronic non-cancer pain [D]	

OR

2.2 Patient has chronic pain related to prior cancer or its treatment [E]

OR

2.3 Patient is receiving palliative care for an advanced illness or pain caused by active cancer [A]

AND

3 - Patient has used opioid medications for a minimum of 4 weeks

AND

4 - One of the following:

4.1 Patient is experiencing fewer than 3 bowel movements in a week

OR

4.2 Patient has not experienced a bowel movement for longer than 2 days

AND

5 - Trial and failure, contraindication, or intolerance to one of the following generics:

- Lactulose
- Polyethylene glycol

AND

6 - Trial and failure, contraindication, or intolerance to Movantik

Product Name: Relistor injection	
Approval Length	4 months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of opioid-induced constipation</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient has chronic non-cancer pain [D]</p> <p style="text-align: center;">OR</p> <p>2.2 Patient has chronic pain related to prior cancer or its treatment [E]</p> <p style="text-align: center;">OR</p> <p>2.3 Patient is receiving palliative care for an advanced illness or pain caused by active cancer [A]</p> <p style="text-align: center;">AND</p> <p>3 - Documentation of positive clinical response to Relistor therapy (e.g., increase in bowel movements)</p>	

Product Name: Relistor tablet	
Approval Length	4 months [B]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of opioid-induced constipation</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient has chronic non-cancer pain [D]</p> <p style="text-align: center;">OR</p> <p>2.2 Patient has chronic pain related to prior cancer or its treatment [E]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has used opioid medications for a minimum of 4 weeks</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Patient is experiencing fewer than 3 bowel movements in a week</p> <p style="text-align: center;">OR</p> <p>4.2 Patient has not experienced a bowel movement for longer than 2 days</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure, contraindication, or intolerance to one of the following generics:</p>	

- Lactulose
- Polyethylene glycol

AND

6 - Trial and failure, contraindication, or intolerance to Movantik

Product Name: Relistor tablet	
Approval Length	4 months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of opioid-induced constipation</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient has chronic non-cancer pain [D]</p> <p style="text-align: center;">OR</p> <p>2.2 Patient has chronic pain related to prior cancer or its treatment [E]</p> <p style="text-align: center;">AND</p> <p>3 - Documentation of positive clinical response to Relistor therapy (e.g., increase in bowel movements)</p>	

2 . Endnotes

- A. The efficacy and safety of Relistor in the treatment of opioid-induced constipation (OIC) in advanced illness patients receiving palliative care was demonstrated in 2 randomized, double-blind, placebo-controlled studies. [1] In these studies, the median age was 68 years (range 21 to 100) and patients had advanced illness and received care to control their symptoms. [1] The majority of patients had a primary diagnosis of incurable cancer; other primary diagnoses included endstage chronic obstructive pulmonary disease (COPD)/emphysema, cardiovascular disease/heart failure, Alzheimer's disease/dementia, HIV/AIDS, or other advanced illnesses. [1]
- B. Authorization limit was set to 4 months because Relistor has not been studied in patients for this indication beyond 4 months. [1]
- C. Stimulant and osmotic laxatives should be tried/failed first before patients are placed on OIC agents (ie, Relistor and Movantik). [3]
- D. The efficacy and safety of Relistor in the treatment of OIC in patients with chronic non-cancer pain were evaluated in a randomized, double-blind, placebo-controlled study comparing 4 weeks of treatment on Relistor 12 mg once daily with placebo. [1] Patients had a history of chronic non-cancer pain for which they were taking opioids. [1] The majority of patients had a primary diagnosis of back pain; other primary diagnoses included joint/extremity pain, fibromyalgia, neurologic/neuropathic pain, and rheumatoid arthritis. [1]
- E. Per discussion with Salix Medical Information, the addition of patients with chronic pain related to prior cancer or its treatment is a clarification of the original intent of the Prescribing Information so as to not inadvertently exclude patients who previously did but do not currently have cancer. This clarification update was not based on any new clinical trial data, but was simply agreed upon during discussion with the FDA and submission of a Prior Approval Supplement. [4]

3 . References

1. Relistor Prescribing Information. Salix Pharmaceuticals, August 2017.
2. DRUGDEX System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Accessed on October 3, 2017.
3. Per clinical consult with gastroenterologist and family medicine specialists, May 20, 2015.
4. Salix Medical Information. Phone conversation. September 26, 2017.

Prior Authorization Guideline

Guideline Name	Continuous Blood Glucose Monitoring (CGM) Systems and Insulin Patch Pumps (Non-formulary and Quantity Limit Exception)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Continuous Blood glucose monitoring systems
<p>CGM devices Intended to be used to measure glucose levels in the interstitial fluid continuously and provide either “on demand” or automated alarms and alerts and blood glucose readings.</p> <p>Insulin Patch Pumps Omnipod, Omnipod Dash, and V-Go are insulin delivery devices intended to be applied to the skin every 24 or 72 hours depending on the product. The devices need to be filled with insulin prior to application.</p>

2 . Criteria

Product Name: Non-formulary or Excluded CGM Systems	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - The non-formulary/excluded CGM product is required because it will interface with the member's insulin pump or other diabetes management products

OR

2 - Documented justification provided for why the non-formulary product is expected to provide benefit over the formulary products

Product Name: CGM Products, Omnipod, Omnipod Dash, V-Go	
Approval Length	12 month(s)
Guideline Type	Quantity Limit Exception
Approval Criteria 1 - Physician confirmation that the patient requires a greater quantity because of unique patient characteristics (e.g., more frequent site change is required; premature device failure; device deployment failure) [A]	

3 . Endnotes

- A. AACE/ACE recommends using CGM whenever indicated to assist patients in reaching glycemic goals safely. CGM helps patients understand their glycemic patterns and obtains blood glucose readings at an adequate frequency to advance their therapy. AACE/ACE recommends GCM be considered in patients who are on intensive insulin therapy, have a history of hypoglycemia unawareness or recurrent hypoglycemia.

4 . References

1. Diabetes Technology: ADA Standards of Medical Care in Diabetes – 2020. Diabetes Care 2020;43(Suppl. 1):S77–S88 | <https://doi.org/10.2337/dc20-S007>.
2. CONSENSUS STATEMENT BY THE AACE AND ACE ON THE COMPREHENSIVE TYPE 2 DIABETES MANAGEMENT ALGORITHM – 2020 EXECUTIVE SUMMARY. ENDOCRINE PRACTICE Vol 26 No. 1 January 2020; 107 – 139.

3. Diabetes Forecast Consumer Guide, continuous blood glucose products:
http://main.diabetes.org/dforg/pdfs/2020/2020-cg-continuous-glucose-monitors.pdf?utm_source=Offline&utm_medium=Print&utm_content=cgms&utm_campaign=DF&s_src=vanity&s_subsrc=cgms
4. Abbot Freestyle: <https://provider.myfreestyle.com/>
5. Medtronic Guardian: <https://www.medtronic.com/us-en/healthcare-professionals/products/diabetes/continuous-glucose-monitoring-systems.html>
6. Eversense Sensionics: <https://hcp.eversenseddiabetes.com/>

Prior Authorization Guideline

Guideline Name	Copiktra (duvelisib)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Copiktra (duvelisib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) after at least two prior therapies.

2 . Criteria

Product Name: Copiktra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)	

AND

2 - Disease is relapsed or refractory

AND

3 - Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Calquence [acalabrutinib], Gazyva [obinutuzumab], Arzerra [ofatumumab], Venclexta [venetoclax], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.) [2]

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Copiktra

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Copiktra Prescribing Information. Verastem, Inc. Needham, MA. December 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed September 28, 2021.

Prior Authorization Guideline

Guideline Name	Copper Chelating Agents - PA, NF
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Cuprimine (penicillamine), Depen (penicillamine)
Wilson's Disease Indicated in the treatment of Wilson's disease. Cystinuria Indicated in the treatment of cystinuria. Rheumatoid Arthritis Indicated in the treatment of severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.
Drug Name: Syprine (trientine)
Wilson's Disease Indicated in the treatment of patients with Wilson's disease who are intolerant of penicillamine.
Drug Name: Cuvrior (trientine tetrahydrochloride)
Wilson's Disease Indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine.

2 . Criteria

Product Name: Brand Cuprimine, Brand Depen, generic penicillamine	
Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of one of the following: [5]</p> <ul style="list-style-type: none"> • Presence of Kayser-Fleisher rings • Serum ceruloplasmin (CPN) less than 20 mg/dL • 24-hour urinary copper excretion greater than 100 mcg • Liver biopsy with copper dry weight greater than 250 mcg/g • ATP7B mutation via genetic testing <p style="text-align: center;">AND</p> <p>3 - Trial and failure, or intolerance to generic Depen (penicillamine) tablets (all formulations except generic penicillamine tablets)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Gastroenterologist • Hepatologist 	

Product Name: Brand Cuprimine, Brand Depen, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cystinuria</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to both of the following:</p> <ul style="list-style-type: none"> • Urinary alkalization therapy [4] • Thiola (tiopronin) [A] <p style="text-align: center;">AND</p> <p>3 - Trial and failure, or intolerance to generic Depen (penicillamine) tablets (all formulations except generic penicillamine tablets)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Nephrologist • Urologist 	

Product Name: Brand Cuprimine, Brand Depen, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of severe, active rheumatoid arthritis

AND

2 - Patient's condition is unresponsive to conventional therapy [e.g., traditional DMARDs (e.g., methotrexate, sulfasalazine), TNF inhibitor (e.g., Humira (adalimumab), Enbrel (etanercept)), Non-TNF biologic (e.g., Rinvoq (upadacitinb), Xeljanz (tofacitinib)]

AND

3 - Trial and failure, or intolerance to generic Depen (penicillamine) tablets (all formulations except generic penicillamine tablets)

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Cuprimine, Brand Depen, generic penicillamine

Diagnosis	Wilson's disease, Cystinuria, Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Brand Syprine, generic trientine, Cuvrior

Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration)

AND

2 - Documentation of one of the following: [5]

- Presence of Kayser-Fleisher rings
- Serum ceruloplasmin (CPN) less than 20 mg/dL
- 24-hour urinary copper excretion greater than 100 mcg
- Liver biopsy with copper dry weight greater than 250 mcg/g
- ATP7B mutation via genetic testing

AND

3 - Trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Hepatologist

Product Name: Brand Syprine, generic trientine, Cuvrior	
Diagnosis	Wilson's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine</p>	

3 . Endnotes

- A. Cystine-binding thiol drugs should be offered to patients with cysteine stones who are unresponsive to dietary modification and urinary alkalinization [3]. Tiopronin should be considered first as it is possibly more effective and associated with fewer adverse events than d-penicillamine.

4 . References

1. Cuprimine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. October 2020.
2. Syprine prescribing information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.
3. Pearle MS, Goldfarb DS, Assimos DG, et al. Medical management of kidney stones: AUA guideline. J Urol. 2014 Aug;192(2):316-24.
4. Fattah H, Hambaroush Y, Goldfarb DS. Cystine nephrolithiasis. Transl Androl Urol. 2014 Sep 1;3(3):228-233. doi: 10.3978/j.issn.2223-4683.2014.07.04.
5. European Association for Study of Liver. EASL Clinical Practice Guidelines: Wilson's disease. J Hepatol. 2012;56(3):671-685.
6. Cuvrior Prescribing Information. Orphan SA. Chicago, IL. May 2022.

Corlanor (ivabradine)

Prior Authorization Guideline

Guideline Name	Corlanor (ivabradine)
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Corlanor (ivabradine)
<p>Chronic Heart Failure Indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic, chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.</p> <p>Heart Failure due to Dilated Cardiomyopathy (DCM) Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.</p> <p>Off Label Uses: Inappropriate Sinus Tachycardia (IST) Has been used for the treatment of inappropriate sinus tachycardia (IST). [7]</p>

2 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic heart failure [3, 5]

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [3, 5, A]

AND

3 - Patient has a left ventricular ejection fraction of less than or equal to 35% [3, 5]

AND

4 - Patient is in sinus rhythm [3, 5]

AND

5 - Patient has a resting heart rate that is greater than or equal to 70 beats per minute [3, 5, E]

AND

6 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [10]

6.1 One of the following:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

6.2 One of the following: [3, 5, 10, B-F]

- bisoprolol
- carvedilol
- metoprolol succinate extended-release

AND

6.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

6.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

7 - Patient has been hospitalized for worsening heart failure in the previous 12 months [3]

AND

8 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of heart failure due to dilated cardiomyopathy

AND

2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [6]

AND

3 - Patient is in sinus rhythm

AND

4 - Patient has an elevated heart rate

AND

5 - Trial and failure, contraindication, or intolerance to one of the following: [1, 4, 6]

- Beta blocker (e.g., bisoprolol, metoprolol succinate extended release)
- Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Diuretic Agent (e.g., spironolactone, furosemide)

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	Inappropriate Sinus Tachycardia (IST) [off-label]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of inappropriate sinus tachycardia (IST) confirmed by both of the following: [7]</p> <ul style="list-style-type: none"> • Sinus heart rate greater than 100 beats per minute at rest • A mean 24 hour heart rate greater than 90 beats per minute <p style="text-align: center;">AND</p> <p>2 - Documentation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.) [7]</p> <p style="text-align: center;">AND</p> <p>3 - Documentation that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, syncope, chest pain, dyspnea, etc.) [8, 9]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a cardiologist</p>	

Product Name: Corlanor	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

3 . Endnotes

- A. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, patients' heart failure was defined as New York Heart Association class II, III or IV [1, 3]
- B. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons for not achieving guideline-recommended doses of beta-blocker therapy were hypotension, fatigue, dyspnea, dizziness, history of cardiac decompensation, and bradycardia [1, 3]
- C. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons that patients were unable to receive beta-blocker therapy were due to a diagnosis of chronic obstructive pulmonary disease, hypotension or asthma [1, 3]
- D. The following are examples of contraindications to beta-blocker therapy but is not a comprehensive list: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second-or-third degree heart block, sick sinus syndrome (without a functional permanent pacemaker) [4]
- E. Corlanor slows the heart rate by inhibiting the cardiac pacemaker If current and therefore heart rate should be at or above 70 beats per minute prior to initiation of therapy to ensure bradycardia does not ensue following initiation of therapy with Corlanor [2]
- F. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [10]

4 . References

1. Corlanor Prescribing Information. Amgen Inc. Thousand Oaks, CA. April 2019.
2. Ivabradine (Corlanor) for heart failure. *Med Lett Drugs Ther.* 2015 May 25; 57 (1469): 75-6.
3. Swedberg K, Komajda M, Bohm M, et al. Ivabradine and outcomes in chronic heart failure (SHIFT): a randomized placebo-controlled study. *Lancet.* 2010 Sep 11;376(9744):875-85.
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc; Updated periodically. Available by subscription at: <http://www.thomsonhc.com/>. Accessed June 25, 2020.
5. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Am Coll Cardiol.* 2017 Aug 8;70(6):776-803.
6. Bonnet D, Berger F, Jokinen E, et al. Ivabradine in children with dilated cardiomyopathy and symptomatic chronic heart failure. *J Am Coll Cardiol.* 2017 Sep 5;70(10):1262-1272.
7. Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. *J Am Coll Cardiol.* 2016 Apr 5;67(13):e27-e115.
8. Cappato R, Castelvechio S, Ricci C, et al. Clinical efficacy of ivabradine in patients with inappropriate sinus tachycardia: a prospective, randomized, placebo-controlled, double-blind, crossover evaluation. *J Am Coll Cardiol.* 2012 Oct 9;60(15):1323-9.

9. Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. *Heart Rhythm*. 2015 Jun;12(6):e41-63.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *Journal of Cardiac Failure*. Published online April 2022.

Prior Authorization Guideline

Guideline Name	Cosentyx (secukinumab) - PA, NF
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Cosentyx (secukinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy.
Psoriatic Arthritis (PsA) Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.
Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.
Non-radiographic Axial Spondyloarthritis (nr-axSpA) Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.
Enthesitis-Related Arthritis (ERA) Indicated for the treatment of active enthesitis-related arthritis in patients 4 years of age and older.

2 . Criteria

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [2]:</p> <ul style="list-style-type: none"> • Greater than or equal to 3% body surface area involvement • Severe scalp psoriasis • Palmoplantar (i.e., palms, soles), facial, or genital involvement <p style="text-align: center;">AND</p> <p>3 - Patient is 6 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a dermatologist</p> <p style="text-align: center;">AND</p> <p>5 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:</p> <ul style="list-style-type: none"> • corticosteroids (e.g., betamethasone, clobetasol) • vitamin D analogs (e.g., calcitriol, calcipotriene) • tazarotene • calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) 	

- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **THREE** of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by **ONE** of the following [2]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction the BSA involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)</p>	

Product Name: Cosentyx	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [2]:</p> <ul style="list-style-type: none"> • Greater than or equal to 3% body surface area involvement • Severe scalp psoriasis • Palmoplantar (i.e., palms, soles), facial, or genital involvement 	

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Both of the following:

6.1 One of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to **THREE** of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.1.2 Both of the following:

6.1.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

6.1.2.2 Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- Reduction the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of active psoriatic arthritis	
AND	
2 - One of the following [4]:	
<ul style="list-style-type: none">• Actively inflamed joints• Dactylitis• Enthesitis• Axial disease	

- Active skin and/or nail involvement

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Orencia (abatacept)
- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline• Reduction in the BSA involvement from baseline	

Product Name: Cosentyx	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [4]:</p> <ul style="list-style-type: none">• Actively inflamed joints• Dactylitis• Enthesitis• Axial disease• Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Patient is 2 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Dermatologist• Rheumatologist <p style="text-align: center;">AND</p> <p>5 - One of the following:</p> <p>5.1 Both of the following:</p> <p>5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:</p> <ul style="list-style-type: none">• Cimzia (certolizumab pegol)• Enbrel (etanercept)	

- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Simponi (golimumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)
- Skyrizi (risankizumab-rzaa)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to BOTH of the following:

- Orencia (abatacept)
- Taltz (ixekizumab)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the BSA involvement from baseline

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes

*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]: <ul style="list-style-type: none">• Disease activity (e.g., pain, fatigue, inflammation, stiffness)• Lab values (erythrocyte sedimentation rate, C-reactive protein level)• Function• Axial status (e.g., lumbar spine motion, chest expansion)	

- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Both of the following:</p> <p>4.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*</p> <ul style="list-style-type: none"> • Cimzia (certolizumab pegol) • Enbrel (etanercept) • Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz • Simponi (golimumab) • Rinvoq (upadacitinib) 	

- Xeljanz/XR (tofacitinib/ER)

AND

4.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

4.2 Both of the following:

4.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

4.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
 Approval Criteria 1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]: <ul style="list-style-type: none">• Disease activity (e.g., pain, fatigue, inflammation, stiffness)• Lab values (erythrocyte sedimentation rate, C-reactive protein level)• Function• Axial status (e.g., lumbar spine motion, chest expansion)• Total active (swollen and tender) joint count	

Product Name: Cosentyx	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to ALL of the following:

- Cimzia (certolizumab pegol)
- Taltz (ixekizumab)
- Rinvoq (upadacitinib)

OR

5.2 Both of the following:

5.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior Cosentyx therapy, defined as no more than a 45-day gap in therapy

AND

5.2.2 Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of active enthesitis-related arthritis	
AND	
2 - Patient is 4 years of age or older	
AND	
3 - Prescribed by or in consultation with a rheumatologist	
AND	
4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum	

duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy as evidenced by at least one of the following [1, 6]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline	

Product Name: Cosentyx	
Diagnosis	Enthesitis-Related Arthritis (ERA)
Approval Length	6 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of active enthesitis-related arthritis	
AND	
2 - Patient is 4 years of age or older	
AND	
3 - Prescribed by or in consultation with a rheumatologist	

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

3 . References

1. Cosentyx prescribing information. Novartis Pharmaceuticals Corp. East Hanover, NJ. July 2023.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol* 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol*. 2019;71(10):1599-1613.
6. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res*. 2019;71(6):717-734.

Cotellic (cobimetinib)

Prior Authorization Guideline

Guideline Name	Cotellic (cobimetinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Cotellic (cobimetinib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.
Histiocytic Neoplasms Indicated as a single agent for the treatment of adult patients with histiocytic neoplasms.

2 . Criteria

Product Name: Cotellic	
Diagnosis	Melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of unresectable or metastatic melanoma

AND

2 - One of the following: [A]

2.1 Patient has a BRAF V600E mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

2.2 Patient has a BRAF V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with Zelboraf (vemurafenib)*

Notes	*This product may require prior authorization.
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Product Name: Cotellic	
Diagnosis	Histiocytic Neoplasms
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of histiocytic neoplasm	

AND

2 - Used as monotherapy

Product Name: Cotellic	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has not experienced disease progression while on therapy	

3 . Endnotes

- A. The cobas 4800 BRAF V600 Mutation Test is an FDA approved option and was used in the pivotal trial. [2, 3] The cobas 4800 BRAF V600 Mutation Test is also listed as the FDA approved companion diagnostic device for Zelboraf (vemurafenib). [3]

4 . References

1. Cotellic Prescribing Information. Genentech, Inc. South San Francisco, CA. October 2022.
2. Larkin J, Ascierto PA, Dréno B, et al. Combined vemurafenib and cobimetinib in BRAF-mutated melanoma. N Engl J Med. 2014;371(20):1867-76.
3. U.S. Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/cm301431.htm>. Accessed May 30, 2023.

Prior Authorization Guideline

Guideline Name	Coverage of Off-Label Non-FDA Approved Indications
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]</p> <p style="text-align: center;">OR</p>	

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.
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Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis is supported as a use in AHFS DI [2]</p> <p>OR</p> <p>1.2 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]</p> <p>OR</p> <p>1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]</p>	

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

Notes	Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.
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2 . Background

Clinical Practice Guidelines		
DRUGDEX Strength of Recommendation [6]		
Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
Class Indeterminate	Evidence Inconclusive	
NCCN Categories of Evidence and Consensus [A]		
Category	Level of Consensus	

1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.
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B	Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a

major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

- B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. Accessed October 24, 2018.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. October 24, 2018.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed October 24, 2018.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-004430. Available at: <https://www.cms.gov/medicare-coverage->

database/details/medicare-coverage-document-details.aspx?MCDId=31#decision.
Accessed October 24, 2018.

5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: <https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf>. Accessed October 24, 2018.
6. Micromedex Healthcare Series.
https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed October 24, 2018.

Prior Authorization Guideline

Guideline Name	Cumulative Morphine Milligram Equivalent (MME) DUR Exceptions
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]</p>	

Product Name: Requested opioid pain medication	
Diagnosis	Pain Due to Cancer
Guideline Type	Administrative

Approval Criteria

1 - Confirmation opioids are being used for the management of cancer pain

Notes	Approval length: Plan year to override MME edit. Note: The termination date of all authorizations for instances when the clinical criteria specifies an Approval Length of "Plan Year" will be 12/31 of the current Plan year with the exception of authorizations granted in the 4th quarter (10/01-12/31) whereby the termination date is 12/31 of the next benefit year. For example, an authorization for Drug X with clinical criteria where the Approval Length indicates "Plan Year" granted on 3/11/2018 will terminate 12/31/2018 and if granted on 10/26/2018 will terminate on 12/31/2019.
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Product Name: Requested opioid pain medication

Diagnosis: Hospice Enrollment

Guideline Type: Administrative

Approval Criteria

1 - Patient is currently enrolled in hospice

Notes	Approval length: Plan year to override MME edit. Note: The termination date of all authorizations for instances when the clinical criteria specifies an Approval Length of "Plan Year" will be 12/31 of the current Plan year with the exception of authorizations granted in the 4th quarter (10/01-12/31) whereby the termination date is 12/31 of the next benefit year. For example, an authorization for Drug X with clinical criteria where the Approval Length indicates "Plan Year" granted on 3/11/2018 will terminate 12/31/2018 and if granted on 10/26/2018 will terminate on 12/31/2019.
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Product Name: Requested opioid pain medication

Diagnosis: Other Pain

Guideline Type: Administrative

Approval Criteria

1 - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required

Notes

Approval length: Plan Year; *MME is calculated using all of the member's current opioid prescriptions
*Note: Ask provider, "Will there be a dose escalation in the patient's opioid utilization in the next 90 days?" If yes, approve MME level 90 daily MME above the rejected level.
Note: The termination date of all authorizations for instances when the clinical criteria specifies an Approval Length of "Plan Year" will be 12/31 of the current Plan year with the exception of authorizations granted in the 4th quarter (10/01-12/31) whereby the termination date is 12/31 of the next benefit year. For example, an authorization for Drug X with clinical criteria where the Approval Length indicates "Plan Year" granted on 3/11/2018 will terminate 12/31/2018 and if granted on 10/26/2018 will terminate on 12/31/2019.

2 . Endnotes

- A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

3 . References

1. Agency Medical Directors Group. Interagency guideline on opioid dosing for chronic non-cancer pain: An educational aid to improve care and safety with opioid therapy. Available at: <http://agencymeddirectors.wa.gov/Files/OpioidGdline.pdf>. Accessed 8/17/2012.
2. Chou R, Fanciullo GJ, Fine PG, et al; American Pain Society-American Academy of Pain Medicine Opioids Guidelines Panel. Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain. J Pain 2009; 10:113-130.
3. Jamison, Robert. Substance abuse treatment for high risk chronic pain patients on opioid therapy. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 7/22/2011. Available from: <http://clinicaltrials.gov/ct2/show/NCT00988962>. NCT00988962.
4. Manchikan L, Abdi S, Atluri S, et al. American Society of Interventional Pain Physicians (ASIPP) Guidelines for Responsible Opioid Prescribing in Chronic Non-Cancer Pain: Part 2 - Guidance. Pain Physician. 2012; 15:S67-S115.

5. Micromedex Healthcare Series. Available at <http://www.thomsonhc.com/home/dispatch>. Accessed August 28, 2012.

Prior Authorization Guideline

Guideline Name	Cyramza (ramucirumab)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Cyramza (ramucirumab)
<p>Gastric Cancer As a single agent, or in combination with paclitaxel, indicated for the treatment of patients with advanced or metastatic, gastric or gastro-esophageal junction adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy.</p> <p>Non-Small Cell Lung Cancer In combination with docetaxel, indicated for the treatment of patients with metastatic non-small cell lung cancer with disease progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Cyramza.</p> <p>Colorectal Cancer In combination with FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil), indicated for the treatment of patients with metastatic colorectal cancer (mCRC) with disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.</p> <p>Hepatocellular Carcinoma Indicated as a single agent, for the treatment of hepatocellular carcinoma in patients who have an alpha fetoprotein of ≥ 400 ng/mL and have been treated with sorafenib.</p>

2 . Criteria

Product Name: Cyramza	
Diagnosis	Gastric or gastro-esophageal junction adenocarcinoma
Approval Length	10 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <p>1.1 Gastric adenocarcinoma</p> <p style="text-align: center;">OR</p> <p>1.2 Gastro-esophageal junction (GEJ) adenocarcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none">• Locally advanced• Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease has progressed on or after one of the following first-line therapies:</p> <p>3.1 Fluoropyrimidine-containing chemotherapy (e.g., fluorouracil, capecitabine) [2]</p> <p style="text-align: center;">OR</p> <p>3.2 Platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) [2]</p>	

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Cyramza

Diagnosis	Gastric or gastro-esophageal junction adenocarcinoma
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Approval Length	10 Months [A]
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on Cyramza therapy

Product Name: Cyramza

Diagnosis	Non-Small Cell Lung Cancer
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Approval Length	10 Months [B]
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Used in combination with docetaxel

AND

3 - Disease has progressed on or after platinum-based chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) [3]

AND

4 - One of the following:

4.1 No EGFR or ALK genomic tumor aberrations are present

OR

4.2 Both of the following:

4.2.1 EGFR or ALK genomic tumor aberrations are present

AND

4.2.2 Patient has had disease progression or intolerance to an approved targeted therapy (e.g., Tarceva, Gilotrif, Xalkori, Zykadia)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Cyramza	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	10 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Cyramza therapy	

Product Name: Cyramza	
Diagnosis	Colorectal Cancer
Approval Length	12 Month
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic colorectal cancer</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with irinotecan or FOLFIRI (irinotecan, folinic acid, and 5-fluorouracil) [5]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has had disease progression on or is intolerant to a prior chemotherapy regimen containing bevacizumab, oxaliplatin, and a fluoropyrimidine</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Cyramza	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on Cyramza therapy</p>	

Product Name: Cyramza	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hepatocellular carcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Patient has an alpha fetoprotein (AFP) greater than or equal to 400 ng/mL [5]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has had disease progression on or after prior Nexavar (sorafenib) therapy or is intolerant to Nexavar (sorafenib)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Cyramza	
Diagnosis	Hepatocellular Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Patient does not show evidence of progressive disease while on Cyramza therapy

3 . Endnotes

- A. In the pivotal Phase 3 RAINBOW trial, ramucirumab plus paclitaxel was associated with a median overall survival of 9.6 months compared to 7.4 months in patients treated with paclitaxel plus placebo ($p < 0.017$). [2]
- B. In the pivotal Phase 3 REVEL trial, ramucirumab plus docetaxel was associated with a median overall survival of 10.5 months compared to 9.1 months in patients treated with docetaxel plus placebo ($p = 0.024$). [1]

4 . References

1. Cyramza prescribing information. Eli Lilly and Company. Indianapolis, IN. May 2019.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Gastric Cancer. v.2.2018. Available by subscription at: http://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed February 25, 2019.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. v.3.2019. Available by subscription at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 25, 2019.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Colon Cancer. v.4.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed February 25, 2019.
5. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. v2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed June 3, 2019.

Cystaran, Cystadrops (cysteamine ophthalmic solution)

Prior Authorization Guideline

Guideline Name	Cystaran, Cystadrops (cysteamine ophthalmic solution)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Cystaran (cysteamine 0.44% ophthalmic solution)
Corneal cystine crystal accumulation Indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis.
Drug Name: Cystadrops (cysteamine 0.37% ophthalmic solution)
Corneal cystine crystal deposits Indicated for the treatment of corneal cystine crystal deposits in adults and children with cystinosis.

2 . Criteria

Product Name: Cystaran, Cystadrops	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystinosis

AND

2 - Diagnosis is confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation [4]

AND

3 - Prescribed by or in consultation with an ophthalmologist or a specialist with experience in treating cystinosis with corneal cystine crystal accumulation [A, 3]

Product Name: Cystaran, Cystadrops

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in corneal crystal formation from baseline)

AND

2 - Prescribed by or in consultation with an ophthalmologist or a specialist with experience in treating cystinosis with corneal cystine crystal accumulation [A, 3]

3 . Endnotes

- A. Ophthalmological considerations: We recommend that the ocular signs and complications of cystinosis are assessed by an experienced ophthalmologist. The

frequency of ophthalmology examination should be tailored according to the needs of the patient and also based on the evaluation of clinical signs, typically 6 months to a year, but occasionally every 3 months. We recommend that findings are documented with digital images as standard-of-care to monitor changes over time [3].

4 . References

1. Cystaran Prescribing Information. Leadiant Biosciences, Inc. Gaithersburg, MD. February 2022.
2. Cystadrops Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ. September 2020.
3. Levtchenko, E., Servais, A et al. Expert Guidance on the Multidisciplinary Management of Cystinosis in Adolescent and Adult Patients. *Clinical Kidney Journal*, 2022, vol. 0, no. 1-10. Available at https://www.researchgate.net/publication/359990974_Expert_guidance_on_the_multidisciplinary_management_of_cystinosis_in_adolescent_and_adult_patients. Accessed May 18, 2022.
4. Niaudet, P et al. Cystinosis. UpToDate. Available at <https://www.uptodate.com/contents/cystinosis>. Accessed May 18, 2022.

Prior Authorization Guideline

Guideline Name	Dacogen (decitabine)/Inqovi (decitabine and cedazuridine) tablets - PA, NF
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Dacogen (decitabine)
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2, and high-risk International Prognostic Scoring System groups.
Drug Name: Inqovi (decitabine and cedazuridine) tablets
Myelodysplastic Syndromes (MDS) Indicated for treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.

2 . Criteria

Product Name: Brand Dacogen, Generic decitabine	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic syndrome</p>	

Product Name: Inqovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic syndrome</p> <p style="text-align: center;">AND</p> <p>2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)</p>	

Product Name: Brand Dacogen, Generic decitabine, Inqovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Inqovi	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic syndrome</p> <p style="text-align: center;">AND</p> <p>2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)</p>	

3 . References

1. Dacogen prescribing information. Astex Pharmaceuticals, Inc. Dublin, CA. November 2021.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc. 2023. Updated periodically. Accessed July 26, 2023.
3. Inqovi prescribing information. Taiho Oncology, Inc. Princeton, NY. March 2022.

Daliresp (roflumilast)

Prior Authorization Guideline

Guideline Name	Daliresp (roflumilast)
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Daliresp (roflumilast)
Chronic obstructive pulmonary disorder (COPD) Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

2 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic obstructive pulmonary disease (COPD) [A, B]

AND

2 - History of COPD exacerbations which require the use of systemic corticosteroids, antibiotics, or hospital admission [C]

AND

3 - Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g. Combivent, Spiriva)

AND

4 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes

Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Product Name: Brand Daliresp, generic roflumilast

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)

Notes

Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

3 . Endnotes

- A. Patients enrolled in the pivotal trials had a forced expiratory volume in 1 second [FEV1] less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7). [1-3]
- B. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) treatment guidelines, moderate COPD is defined as FEV1 less than 80% but greater than or equal to 50%; severe COPD is defined as FEV1 less than 50% but greater than or equal to 30%; and very severe COPD is defined as FEV1 less than 30%. [4]
- C. In the pivotal studies the rate of moderate exacerbations was defined as requiring intervention with systemic glucocorticosteroids. Severe exacerbations were defined as leading to hospitalization and/or to death. [1]

4 . References

- 1. Daliresp Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. March 2020.
- 2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: <https://www.micromedexsolutions.com/>. Accessed August 24, 2021.
- 3. FDA Summary Review. Accessed at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000SumR.pdf. Accessed August 24, 2021.
- 4. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2022 report). Accessed at: https://goldcopd.org/wp-content/uploads/2021/12/GOLD-REPORT-2022-v1.1-22Nov2021_WMV.pdf. Accessed August 4, 2022.

Daraprim (pyrimethamine)

Prior Authorization Guideline

Guideline Name	Daraprim (pyrimethamine)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Daraprim (pyrimethamine)
Treatment of toxoplasmosis Indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide, since synergism exists with this combination.

2 . Criteria

Product Name: Brand Daraprim, generic pyrimethamine	
Diagnosis	Toxoplasmosis
Approval Length	12 Months [A, B]
Guideline Type	Prior Authorization
Approval Criteria 1 - Both of the following:	

1.1 One of the following:

1.1.1 Patient is using pyrimethamine for one of the following: [2, 3]

- Active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis)
- Secondary prophylaxis of toxoplasmosis
- Treatment of congenital toxoplasmosis

OR

1.1.2 All of the following: [2]

1.1.2.1 Patient is using pyrimethamine for primary prophylaxis of toxoplasmosis

AND

1.1.2.2 Patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX)

AND

1.1.2.3 One of the following:

1.1.2.3.1 Patient has been re-challenged with trimethoprim-sulfamethoxazole (TMP-SMX) using a desensitization protocol and is still unable to tolerate

OR

1.1.2.3.2 Evidence of life-threatening reaction to trimethoprim-sulfamethoxazole (TMP-SMX) in the past (e.g., toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome)

AND

1.2 Prescribed by or in consultation with an infectious disease specialist

Product Name: Brand Daraprim, generic pyrimethamine

Diagnosis	Malaria (off-label)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC) [5]</p>	

3 . Endnotes

- A. Prescriber should consider discontinuation of primary prophylaxis if CD4 is greater than 200 cells/mm³ for more than 3 months after institution of combination antiretroviral therapy. [2]
- B. Prescriber should consider discontinuation of secondary prophylaxis if CD4 is greater than 200 cells/mm³ for more than 6 months after institution of combination antiretroviral therapy. [2]

4 . References

1. Daraprim Prescribing Information. Viera Pharmaceuticals. New York, NY. August 2017.
2. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-opportunistic-infection/whats-new-guidelines>. Accessed May 5, 2022.
3. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Exposed and HIV-Infected Children. https://clinicalinfo.hiv.gov/sites/default/files/guidelines/archive/OI_Guidelines_Pediatrics_2022_01_04.pdf. Accessed May 5, 2022.
4. Parasites - Toxoplasmosis (Toxoplasma infection). https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html#tx. Accessed May 5, 2022
5. Centers for Disease Control and Prevention. CDC Yellow Book 2020: Health Information for International Travel. New York: Oxford University Press; 2020. <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria>. Accessed May 5, 2022.

Daurismo (glasdegib)

Prior Authorization Guideline

Guideline Name	Daurismo (glasdegib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Daurismo (glasdegib)
Acute Myeloid Leukemia (AML) Indicated for use in combination with low-dose cytarabine, for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adult patients who are greater than or equal to 75 years old or who have comorbidities that preclude use of intensive induction chemotherapy. Limitation of Use: Daurismo has not been studied in patients with the comorbidities of severe renal impairment or moderate-to-severe hepatic impairment.

2 . Criteria

Product Name: Daurismo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of newly-diagnosed acute myeloid leukemia (AML)

AND

2 - Used in combination with low-dose cytarabine

AND

3 - One of the following:

3.1 Patient is greater than or equal to 75 years old

OR

3.2 Patient has comorbidities that preclude use of intensive induction chemotherapy [A]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Daurismo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Examples of comorbid conditions are severe cardiac disease, ECOG performance status greater than or equal to 2, or baseline creatinine greater than 1.3 mg/dL. [2]

4 . References

1. Daurismo Prescribing Information. Pfizer Inc. New York, NY. November 2018.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v.3.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed January 8, 2020.

Prior Authorization Guideline

Guideline Name	DAW Override Exception
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Guideline Note:

Effective Date:	1/1/2023
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1 . Criteria

Product Name: Brand drugs with two or more generic equivalents available	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - General requirements for review include all of the following:</p> <p>1.1 The drug meets other required reviews if applicable (e.g., PA, ST, NF)</p> <p style="text-align: center;">AND</p> <p>1.2 The request is for DAW review</p>	

AND

1.3 The requested drug is an MSC=O drug

AND

1.4 The product selection fee is applied on the requested drug's claim

AND

1.5 The plan allows DAW reviews

AND

2 - Patient has tried at least two generic equivalents of the requested drug from different manufacturers

AND

3 - Both of the following:

3.1 Patient has had a trial and failure, contraindication, or intolerance to the generic products

AND

3.2 Submission of documentation (chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - One of the following:

4.1 Requested drug is FDA-approved for the condition being treated

OR

4.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Product Name: Brand drugs with only one generic equivalent available

Approval Length	12 month(s)
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Guideline Type	Administrative
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Approval Criteria

1 - General requirements for review include all of the following:

1.1 The drug meets other required reviews if applicable (e.g., PA, ST, NF)

AND

1.2 The request is for DAW review

AND

1.3 The requested drug is an MSC=O drug

AND

1.4 The product selection fee is applied on the requested drug's claim

AND

1.5 The plan allows DAW reviews

AND

2 - Patient has tried one generic equivalent of the requested drug

AND

3 - Both of the following:

3.1 Patient has had a trial and failure, contraindication, or intolerance to the generic product

AND

3.2 Submission of documentation (chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

AND

4 - One of the following:

4.1 Requested drug is FDA-approved for the condition being treated

OR

4.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Daybue (trofinetide)

Prior Authorization Guideline

Guideline Name	Daybue (trofinetide)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Daybue (trofinetide)
Rett Syndrome Indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older.

2 . Criteria

Product Name: Daybue	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Rett syndrome	

AND

2 - One of the following:

2.1 Presence of ALL of the following clinical signs and symptoms: [3-8]

- A pattern of development, regression, then recovery or stabilization
- Partial or complete loss of purposeful hand skills such as grasping with fingers, reaching for things, or touching things on purpose
- Partial or complete loss of spoken language
- Repetitive hand movements, such as wringing the hands, washing, squeezing, clapping, or rubbing
- Gait abnormalities, including walking on toes or with an unsteady, wide-based, stiff-legged gait

OR

2.2 Molecular genetic testing confirms mutations in the MECP2 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Prescribed by or in consultation with one of the following: [A, 2]

- Geneticist
- Neurologist

Product Name: Daybue	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

- A. A neurologist, or geneticist should be consulted to confirm the diagnosis of Rett syndrome. [9]

4 . References

1. Daybue Prescribing Information. Acadia Pharmaceuticals Inc. San Diego, CA March 2023.
2. National Institute of Neurological Disorders and Stroke. Rett Syndrome. Available at: <https://www.ninds.nih.gov/health-information/disorders/rett-syndrome>. Accessed April 3, 2023.
3. Clinicaltrials.gov. Study of Trofinetide for the Treatment of Girls and Women With Rett Syndrome (LAVENDER™). Available at: <https://clinicaltrials.gov/ct2/results?cond=&term=NCT04181723&cntry=&state=&city=&dist=>. Accessed April 3, 2023.
4. Eunice Kennedy Shriver National Institute of Child Health and Human Development. Rett syndrome. Available at: <https://www.nichd.nih.gov/health/topics/rett/conditioninfo/diagnosed>. Accessed April 3, 2023.
5. Rett syndrome. Available at: <https://raisingchildren.net.au/disability/guide-to-disabilities/assessment-diagnosis/rett-syndrome>. Accessed April 3, 2023.
6. International Rett Syndrome Foundation. Available at: <https://www.rettsyndrome.org/about-rett-syndrome/rett-syndrome-diagnosis/>. Accessed April 3, 2023.
7. Neul, J., Kaufmann, W., et al. Rett Syndrome: Revised Diagnostic Criteria and Nomenclature. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058521/>. Accessed April 7, 2023.
8. Clinical consult with pediatric neurologist. April 17, 2023.
9. Optum May P & T

Prior Authorization Guideline

Guideline Name	Deferasirox products
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Jadenu Sprinkle (deferasirox)
<p>Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of use: The safety and efficacy of Jadenu when administered with other iron chelation therapy have not been established.</p> <p>Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. This indication is approved under accelerated approval based on a reduction of liver iron concentrations (to less than 5 mg Fe/g dw) and serum ferritin levels. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Limitations of use: The safety and efficacy of Jadenu when administered with other iron chelation therapy have not been established.</p> <p>Off Label Uses: Myelodysplastic syndrome (MDS) Low to intermediate risk myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]</p>
Drug Name: Exjade (deferasirox)

Treatment of Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of use: Controlled clinical trials of Exjade with myelodysplastic syndromes (MDS) and chronic iron overload due to blood transfusions have not been performed. The safety and efficacy of Exjade when administered with other iron chelation therapy have not been established.

Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. This indication is based on achievement of an LIC less than 5 mg Fe/g dw. An improvement in survival or disease-related symptoms has not been established. Limitations of use: The safety and efficacy of Exjade when administered with other iron chelation therapy have not been established.

Off Label Uses: Myelodysplastic syndrome (MDS) Low to intermediate risk myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]

2 . Criteria

Product Name: Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age or older</p>	

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient has a baseline ferritin level more than 1,000 mcg/L

AND

4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells

Product Name: Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of myelodysplastic syndrome	
AND	
2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient	
AND	
3 - Patient has received more than 20 red blood cell transfusions	
AND	
4 - Trial and failure of generic deferasirox	

Product Name: Generic deferasirox	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient

AND

3 - Patient has received more than 20 red blood cell transfusions

Product Name: Brand Jadenu Sprinkle, Brand Exjade

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)

AND

2 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p>	

Product Name: Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 10 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher</p> <p style="text-align: center;">AND</p> <p>4 - Serum ferritin level greater than 300 mcg/L</p>	

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 10 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher</p> <p style="text-align: center;">AND</p> <p>4 - Serum ferritin level greater than 300 mcg/L</p>	

Product Name: Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher</p> <p style="text-align: center;">AND</p> <p>2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure of generic deferasirox</p>	

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher</p> <p style="text-align: center;">AND</p> <p>2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p>	

3 . References

1. Exjade Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. December 2018.
2. Cappellini MD, Cohen A, Piga A, et al. A Phase III study of deferasirox (ICL670), a once-daily oral iron chelator, in patients with [beta]-thalassemia. *Blood*. 2006;107(9):3455-62.
3. Cappellini MD. Iron-chelating therapy with the new oral agent ICL670 (Exjade). *Best Pract Res Clin Haematol*. 2005;18(2):289-98.
4. Galanello R, Piga A, Alberti D, Rouan MC, Bigler H, Sechaud R. Safety, tolerability, and pharmacokinetics of ICL670, a new orally active iron-chelating agent in patients with transfusion-dependent iron overload due to beta-thalassemia. *J Clin Pharmacol*. 2003;43(6):565-72.
5. Nisbet-Brown E, Olivieri NF, Giardina PJ, et al. Effectiveness and safety of ICL670 in iron-loaded patients with thalassaemia: a randomized, double-blind, placebo-controlled, dose-escalation trial. *Lancet*. 2003;361(9369):1597-602.
6. International Association of Sickle Cell Nurses and Physician Assistants. *Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload*. 2008. http://www.iascnapa.org/guidelines/Guidelines_IronOverload.pdf. Accessed on May 31, 2019.
7. Ho PJ, Tay L, Linderman R, Catley L, Bowden DK. Australian guidelines for the assessment of iron overload and iron chelation in transfusion-dependent thalassaemia major, sickle cell disease and other congenital anaemias. *Intern Med J*. 2011;41(7):516-24.
8. Angelucci E, Barosi G, Camaschella C, et al. Italian Society of Hematology practice guidelines for the management of iron overload in thalassemia major and related disorders. *Haematologica*. 2008;93(5):741-52.
9. Porter JB and Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. 2010 Dec;24(6):1109-30.
10. Jadenu Sprinkle Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. July 2020.
11. AHFS Drug Information (Adult and Pediatric) [Internet database]. Bethesda, Maryland. Lexicomp, Inc. Updated periodically. Available by subscription at: <http://online.lexi.com/>. Accessed on April 28, 2020.

Demser (metyrosine)

Prior Authorization Guideline

Guideline Name	Demser (metyrosine)
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Guideline Note:

Effective Date:	7/1/2022
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1 . Indications

Drug Name: Demser (metyrosine)
Pheochromocytoma Indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery, management of patients when surgery is contraindicated, and chronic treatment of patients with malignant pheochromocytoma. Metyrosine capsules are not recommended for the control of essential hypertension.

2 . Criteria

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Preoperative preparation
Approval Length	1 Time(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractionated metanephrines

AND

2 - Medication is being used for preoperative preparation

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin)
- beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

4 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:	
<ul style="list-style-type: none">• plasma free metanephrines	

- urinary fractionated metanephrines

AND

2 - Patient with hormonally active (catecholamine excess) pheochromocytoma

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Chronic treatment due to malignant pheochromocytoma

AND

4 - Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

5 - Medication will not be used to control essential hypertension

AND

6 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Provider who specializes in the management of pheochromocytoma

Product Name: Brand Demser, generic metyrosine

Diagnosis	Treatment of pheochromocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks)</p>	

3 . References

1. Metyrosine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. November 2020.
2. Naruse M, Satoh F, Tanabe A, et al. Efficacy and safety of metyrosine in pheochromocytoma/paraganglioma: a multi-center trial in Japan. *Endocrine Journal*. 2018;65(3):359-371.
3. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(6):1915-1942.

Descovy (emtricitabine/tenofovir alafenamide)

Prior Authorization Guideline

Guideline Name	Descovy (emtricitabine/tenofovir alafenamide)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
<p>Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 25 kg and less than 35 kg.</p> <p>HIV-1 Pre-exposure Prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated</p>

2 . Criteria

Product Name: Descovy

Diagnosis	Treatment of HIV Infection
Approval Length	24 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Descovy is being used for the treatment of HIV infection</p>	

Product Name: Descovy	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Descovy is being used for HIV Pre-exposure Prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has a history of intolerance or contraindication to Truvada</p>	

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. October 2019.

Diacomit (stiripentol)

Prior Authorization Guideline

Guideline Name	Diacomit (stiripentol)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Diacomit (stiripentol)
Dravet syndrome (DS) Indicated for the treatment of seizures associated with Dravet syndrome in patients taking clobazam who are 6 months of age or older and weighing 7 kg or more. There are no clinical data to support the use of DIACOMIT as monotherapy in Dravet syndrome.

2 . Criteria

Product Name: Diacomit	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2 - Used in combination with clobazam

AND

3 - BOTH of the following:

- Patient is 6 months of age or older
- Patient weighs 7kg or more

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Diacomit

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Used in combination with clobazam

3 . References

1. Diacomit Prescribing Information. Biocodex. Gentilly, France. July 2022.

Dibenzylamine (phenoxybenzamine)

Prior Authorization Guideline

Guideline Name	Dibenzylamine (phenoxybenzamine)
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Guideline Note:

Effective Date:	7/1/2022
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1 . Indications

Drug Name: Dibenzylamine (phenoxybenzamine)
Pheochromocytoma Indicated in the treatment of pheochromocytoma to control episodes of hypertension and swelling.

2 . Criteria

Product Name: Brand Dibenzylamine, generic phenoxybenzamine	
Diagnosis	Pheochromocytoma
Approval Length	1 Time(s) [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: [2]	

- plasma free metanephrines
- urinary fractionated metanephrines

AND

2 - Medication is being used for preoperative preparation [A,1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following:

- doxazosin
- terazosin
- prazosin

AND

4 - Treatment will also include a high-sodium diet and fluid intake [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Endocrine surgeon

3 . Endnotes

- A. Phenoxybenzamine is most commonly used for preoperative control of blood pressure. Its only current clinical use is in preparing patients with pheochromocytoma for surgery. [1]
- B. Retrospective studies report that initiation of high-sodium diet a few days after the start of alpha-adrenergic receptor blockade reverses blood volume contraction, prevents orthostatic hypotension before surgery, and reduces the risk of significant hypotension after surgery. [2]

4 . References

1. Farrugia F, Martikos G, Tzanetis P, et al. Pheochromocytoma, diagnosis and treatment: Review of the literature. *Endocrine Regulations*. 2017;51(3):168-181.
2. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(6):1915-1942.
3. Phenoxybenzamine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2020.

Dojolvi (triheptanoin)

Prior Authorization Guideline

Guideline Name	Dojolvi (triheptanoin)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Dojolvi (triheptanoin)
Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD) Indicated as a source of calories and fatty acids for the treatment of pediatric and adult patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD).

2 . Criteria

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD) has been confirmed by at least two of the following:

- Disease specific elevation of acyl-carnitines on a newborn blood spot or in plasma
- Low enzyme activity in cultured fibroblasts
- One or more known pathogenic mutations in CPT2, ACADVL, HADHA, or HADHB

AND

2 - Not used with any other medium-chain triglyceride (MCT) product

AND

3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)

Product Name: Dojolvi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Prescriber attests to continued need of therapy [A]	
AND	
2 - Not used with any other medium-chain triglyceride (MCT) product	
AND	
3 - Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease-related dietary management (e.g., geneticist, cardiologist, gastroenterologist, etc.)	

3 . Endnotes

- A. This reauthorization criteria was recommended by the clinical consultant since LA-FAODs are progressive even with therapy. Patients will need lifelong therapy even though positive clinical response may not be seen.

4 . References

1. Dojolvi (triheptanoin) prescribing information. Ultragenyx Pharmaceutical Inc. Novato, CA. November 2021.
2. Per clinical consult with internal medicine/pediatric specialist, September 24, 2020.

Doptelet (avatrombopag)

Prior Authorization Guideline

Guideline Name	Doptelet (avatrombopag)
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Guideline Note:

Effective Date:	6/15/2022
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1 . Indications

Drug Name: Doptelet (avatrombopag)
Thrombocytopenia in Patients with Chronic Liver Disease (CLD) Indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.
Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name: Doptelet	
Diagnosis	Thrombocytopenia in Patients with Chronic Liver Disease (CLD)
Approval Length	1 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of thrombocytopenia

AND

2 - Patient has chronic liver disease

AND

3 - Patient is scheduled to undergo a procedure

AND

4 - Baseline platelet count is less than 50,000/mcL [1, 5]

AND

5 - Trial and failure, contraindication, or intolerance to Mulpleta (lusutrombopag)

Product Name: Doptelet

Diagnosis	Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Chronic immune (idiopathic) thrombocytopenic purpura (ITP)

- Relapsed/refractory ITP [3]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [1-4]

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding [3]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Doptelet	
Diagnosis	Thrombocytopenia in Patients with Chronic Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding	

3 . References

1. Doptelet Prescribing Information. AkaRx, Inc. Durham, NC. July 2021.
2. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: <https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for>. Accessed February 15, 2021.
3. Per clinical consult with hematologist/oncologist. June 20, 2018.
4. Jurczak W, Chojnowski K, Mayer J, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. *Br J Haematol.* 2018;183(3):479-490.
5. Terrault N, Chen YC, Izumi N, et al. Avatrombopag before procedures reduces need for platelet transfusion in patients with chronic liver disease and thrombocytopenia. *Gastroenterology.* 2018 Sep;155(3):705-718. doi: 10.1053/j.gastro.2018.05.025. Epub 2018 May 17.

Duobrii (halobetasol propionate and tazarotene)

Prior Authorization Guideline

Guideline Name	Duobrii (halobetasol propionate and tazarotene)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Duobrii (halobetasol propionate and tazarotene)
Plaque Psoriasis Indicated for the topical treatment of plaque psoriasis in adults.

2 . Criteria

Product Name: Duobrii	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of plaque psoriasis	

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Both of the following:

3.1 Trial and failure, intolerance or contraindication to one high potency corticosteroid topical treatment (e.g., halobetasol propionate, clobetasol propionate, fluocinonide)

AND

3.2 Trial and failure or intolerance to tazarotene

3 . Background

Clinical Practice Guidelines

Table 1. Relative Potency of Selected Topical Corticosteroid Products [2-4]

Drug	Dosage Form	Strength
Very High Potency		
Augmented betamethasone dipropionate (Diprolene)	Ointment	0.05%
Clobetasol propionate (Temovate)	Cream, Ointment	0.05%
Diflorasone diacetate (Psorcon)	Ointment	0.05%
Desoximetasone (Topicort)	Topical Spray	0.25%
Fluocinonide (Vanos)	Cream	0.1%
Flurandrenolide (Cordran)	Tape (roll)	4 mcg/m ²
Halobetasol propionate (Ultravate)	Cream, Ointment Lotion	0.05%
High Potency		

Amcinonide (Cyclocort, Amcort)	Cream, Lotion, Ointment	0.1%
Augmented betamethasone dipropionate (Diprolene, Diprolene AF)	Cream	0.05%
Betamethasone dipropionate (Diprosone)	Cream, Ointment	0.05%
Betamethasone valerate (Valisone)	Ointment	0.1%
Clobetasol propionate (Impoyz)	Cream	0.025%
Desoximetasone (Topicort)	Cream, Ointment,	0.25%
	Cream, Gel	0.05%
Diflorasone diacetate (Florone, Maxiflor)	Cream, Ointment (emollient base)	0.05%
Fluocinonide (Lidex, Lidex-E)	Cream, Cream (emollient base), Ointment, Gel	0.05%
Fluticasone propionate (Cultivate)	Ointment	0.005%
Halcinonide (Halog)	Cream, Ointment	0.1%
Halobetasol propionate (Bryhali)	Lotion	0.01%
Mometasone furoate (Elocon)	Ointment	0.1%
Triamcinolone acetonide (Aristocort A, Kenalog)	Cream, Ointment	0.5%

4 . References

1. Duobrii Prescribing Information. Bausch Health Americas, Inc. Bridgewater, NJ. April 2019.
2. Menter A, Korman N, Elmets C, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Amer. Acad. of Derm. 2009;60:643-59.
3. National Psoriasis Foundation. Psoriasis and Psoriatic Arthritis Pocket Guide: Treatment Algorithms and Management Options. Available at <http://www.psoriasis.org/health-care-providers/treating-psoriasis>. Accessed June 12, 2019.
4. UptoDate Online [internet database]. Waltham, MA. UptoDate, Inc. Updated periodically. Available by subscription at: www.uptodate.com. Accessed June 12, 2019.

Prior Authorization Guideline

Guideline Name	Dupixent (dupilumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Dupixent (dupilumab)
<p>Atopic Dermatitis Indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.</p> <p>Asthma Indicated as an add-on maintenance treatment of patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. Limitations of use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.</p> <p>Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) Indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).</p> <p>Eosinophilic Esophagitis (EoE) Indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).</p> <p>Prurigo Nodularis (PN) Indicated for the treatment of adult patients with prurigo nodularis (PN).</p>

2 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	16 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate-to-severe atopic dermatitis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <ul style="list-style-type: none">• Involvement of at least 10% body surface area (BSA)• SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A] <p style="text-align: center;">AND</p> <p>3 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to at least ONE of the following [2]:</p> <ul style="list-style-type: none">• Medium or higher potency topical corticosteroid• Pimecrolimus cream• Tacrolimus ointment• Eucrisa (crisaborole) ointment <p style="text-align: center;">AND</p> <p>4 - Patient is 6 months of age or older</p> <p style="text-align: center;">AND</p>	

5 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:	
<ul style="list-style-type: none">• Reduction in BSA involvement from baseline• Reduction in SCORAD index value from baseline	

Product Name: Dupixent	
Diagnosis	Eosinophilic Asthma
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderate to severe asthma	
AND	

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pretreatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [C, D]

AND

3 - Patient is 6 years of age or older

AND

4 - One of the following:

4.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [4, 5, 7]

OR

4.2 Prior asthma-related hospitalization within the past 12 months [4, 5, E]

AND

5 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

5.1 Both of the following [4, 5, 7]:

- High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day]
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

5.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent

Diagnosis	Eosinophilic Asthma
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent

Diagnosis	Oral Corticosteroid Dependent Asthma
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Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe asthma</p> <p style="text-align: center;">AND</p> <p>2 - Age greater than or equal to 6 years</p> <p style="text-align: center;">AND</p> <p>3 - Patient is currently dependent on oral corticosteroids for the treatment of asthma</p> <p style="text-align: center;">AND</p> <p>4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:</p> <p>4.1 Both of the following [6]:</p> <ul style="list-style-type: none"> • High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] • Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) <p style="text-align: center;">OR</p> <p>4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p>	

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose)</p> <p style="text-align: center;">AND</p> <p>2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Pulmonologist • Allergist/Immunologist 	

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

AND

2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]

AND

3 - Presence of at least 2 of the following symptoms for at least 12 weeks:

- Nasal blockage/obstruction/congestion
- Nasal discharge (anterior/posterior nasal drip)
- Facial pain/pressure
- Reduction or loss of smell

AND

4 - Systemic corticosteroid treatment for nasal polyps at least once in the last two years or prior nasal polyp surgery > 6 months ago

AND

5 - Used in combination with another agent for CRSwNP [F]

AND

6 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NC; 0-3 scale])</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with another agent for CRSwNP [F]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Allergist/Immunologist • Otolaryngologist • Pulmonologist 	

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of eosinophilic esophagitis (EoE)</p>	

AND

2 - Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain) [13-15]

AND

3 - Patient has at least 15 intraepithelial eosinophils per high power field (HPF) [1, 13-15]

AND

4 - Other causes of esophageal eosinophilia have been excluded [13-15]

AND

5 - Both of the following:

- Patient is at least 12 years of age
- Patient weighs at least 40 kg

AND

6 - Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following:

- Proton pump inhibitors (e.g., pantoprazole, omeprazole)
- Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

AND

7 - Prescribed by or in consultation with one of the following:

- Gastroenterologist

- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline [1, 13-15]:</p> <ul style="list-style-type: none"> • Symptoms (e.g., dysphagia, food impaction, heartburn, chest pain) • Histologic measures (e.g., esophageal intraepithelial eosinophil count) • Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures) 	

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of prurigo nodularis (PN)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has at least 20 nodular lesions</p>	

AND

3 - Trial and failure, contraindication, or intolerance to one previous PN treatment (e.g., topical corticosteroids, topical calcineurin inhibitors [pimecrolimus, tacrolimus], topical capsaicin) [16, 17]

AND

4 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Dermatologist

Product Name: Dupixent	
Diagnosis	Prurigo Nodularis (PN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:	
<ul style="list-style-type: none">• Reduction in the number of nodular lesions from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

3 . Background

Clinical Practice Guidelines
Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1

	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 2. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [7]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320

Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400
<p>DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.</p> <p><i>This is not a table of equivalence</i>, but instead, suggested total daily doses for the ‘low’, ‘medium’ and ‘high’ dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country - specific depending on local availability, regulatory labelling and clinical guidelines.</p> <p>For new preparations, including generic ICS, the manufacturer’s information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.</p>			

4 . Endnotes

- A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [10, 11] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score (A/5 + 7B/2 + C) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [12]
- B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well

as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy.

- C. In AS Trial 2, reductions in exacerbations were significant in the subgroup of subjects with baseline blood eosinophils greater than or equal to 150 cells/mcL. In subjects with baseline blood eosinophil count less than 150 cells/mcL, similar severe exacerbation rates were observed between Dupixent and placebo. [1]
- D. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [3]
- E. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
- F. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Dupixent Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. October 2022.
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4. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high dose inhaled corticosteroids plus a long-acting B2 agonist: a randomized double-blind placebo-controlled pivotal phase 2b dose-ranging trial. *Lancet*. 2016;388:31-44.
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6. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. *N Engl J Med*. 2018; 378(26):2475-85.
7. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
8. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-85.
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 15. Dellon ES, Khoury P, Muir AB, et al. A clinical severity index for eosinophilic esophagitis: development, consensus, and future directions. *Gastroenterology*. 2022;1-18 [Epub ahead of print].
 16. Williams KA, Huang AH, Belzberg M, et al. Prurigo nodularis: pathogenesis and management. *J Am Acad Dermatol*. 2020;83(6):1567-75.
 17. Leis M, Fleming P, Lynde CW. Prurigo nodularis: review and emerging treatments. *Skin Therapy Lett*. 2021;26(3):5-8.

Dysport (abobotulinumtoxinA)

Prior Authorization Guideline

Guideline Name	Dysport (abobotulinumtoxinA)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Dysport (abobotulinumtoxinA)
Cervical Dystonia Indicated for the treatment of cervical dystonia in adults.
Glabellar Lines Indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients less than 65 years of age. Note: This indication is generally a plan exclusion. Drugs prescribed to primarily improve or otherwise modify the member's external appearance are excluded from coverage.
Spasticity Indicated for the treatment of spasticity in patients 2 years of age and older.

2 . Criteria

Product Name: Dysport	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2, 3]</p>	

Product Name: Dysport	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have elapsed since the last treatment [A]</p>	

Product Name: Dysport	
Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of spasticity [3]</p> <p style="text-align: center;">AND</p>	

2 - Patient is 2 years of age or older

Product Name: Dysport

Diagnosis	Spasticity
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed since the last treatment [A]

3 . Endnotes

- A. In the pivotal clinical trial, doses of 500 Units and 1000 Units were divided among selected muscles. Repeat treatment should be administered when the effect of a previous injection has diminished, but no sooner than 12 weeks after the previous injection. A majority of patients in clinical studies were retreated between 12-16 weeks; however some patients had a longer duration of response, i.e., 20 weeks. [1]

4 . References

1. Dysport Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Truong D, Duane DD, Jankovic J, et al. Efficacy and safety of botulinum type A toxin (Dysport) in cervical dystonia: results of the first US randomized, double-blind, placebo-controlled study. *Mov Disord.* 2005;20(7):783-791.
3. Simpson D, Hallett M, Ashman E et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache. *Neurology.* 2016;86(19):1818-1826.

Egrifta (tesamorelin)

Prior Authorization Guideline

Guideline Name	Egrifta (tesamorelin)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Egrifta SV (tesamorelin)
Excess Abdominal Fat Reduction in HIV-associated Lipodystrophy Indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy. Limitations of use: 1) Long-term cardiovascular safety of EGRIFTA SV has not been established. Consider risk/benefit of continuation of treatment in patients who have not had a reduction in visceral adipose tissue. 2) Not indicated for weight loss management as it has a weight neutral effect. 3) There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking EGRIFTA SV.

2 . Criteria

Product Name: Egrifta SV	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV-associated lipodystrophy

AND

2 - Patient is 18 years of age or older [A]

AND

3 - One of the following: [B]

- Waist-circumference of greater than or equal to 95 cm (37.4 inches) in men
- Waist-circumference of greater than or equal to 94 cm (37 inches) for women

AND

4 - One of the following: [B]

- Waist-to-hip ratio of greater than or equal to 0.94 for men
- Waist-to-hip ratio of greater than or equal to 0.88 for women

AND

5 - Body mass index (BMI) of greater than 20 kg/m² [B]

AND

6 - Fasting blood glucose (FBG) levels less than or equal to 150 mg/dL (8.33 mmol/L) [B]

AND

7 - Patient has been on a stable regimen of antiretrovirals (e.g., NRTIs, NNRTI, Protease Inhibitors, Integrase Inhibitors) for at least 8 weeks [C]

Product Name: Egrifta SV	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of clinical improvement (e.g., improvement in visceral adipose tissue [VAT], decrease in waist circumference, belly appearance, etc.) while on therapy</p>	

3 . Endnotes

- A. Study sponsors requested a waiver for pediatric studies in children less than 18 years of age, and this waiver was granted by the FDA due to concerns that among patients with open epiphyses, excess growth hormone and IGF-1 may result in linear growth acceleration and excessive growth. [2]
- B. Both pivotal studies included patients 18 to 65 years of age (mean age, 48 years) who met the waist circumference criteria [95 cm (37.4 inches) or greater for men; 94 cm (37 inches) or greater for women], who met the waist-to-hip ratio criteria (0.94 or greater for men; 0.88 or greater for women), who had a fasting blood glucose of less than 150 mg/dL (8.33 mmol/L) criteria, and who had been on a stable antiretroviral regimen for at least 8 weeks. Patients with a BMI (body mass index) of 20 kg/m² or less and patients with diabetes [fasting blood glucose (FBG) levels > 150 mg/dL] were among those excluded. [2-6]
- C. The 8 weeks of antiretroviral regimen listed in the criteria is based on the inclusion criteria in the pivotal study. [2-6]

4 . References

1. Egrifta SV Prescribing Information. Theratechnologies, Inc. Montreal, Canada. October 2019.
2. Egrifta FDA Medical Review. September 15, 2010. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022505Orig1s000TOC.cfm. Accessed May 20, 2021.
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Elmiron (pentosan polysulfate sodium)

Prior Authorization Guideline

Guideline Name	Elmiron (pentosan polysulfate sodium)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Elmiron (pentosan polysulfate sodium)
Interstitial Cystitis Indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

2 . Criteria

Product Name: Elmiron	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of interstitial cystitis	

AND

2 - Patient has bladder pain or discomfort

AND

3 - One of the following:

3.1 Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to two of the following: [2]

- Amitriptyline
- Cimetidine
- Hydroxyzine

OR

3.2 For continuation of prior therapy

Product Name: Elmiron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Elmiron Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. June 2020.
2. Hanno PM, Erickson D, Moldwin R, et al. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. J Urol . 2015 May;193(5):1545-53. doi: 10.1016/j.juro.2015.01.086.

Prior Authorization Guideline

Guideline Name	Elyxyb (celecoxib) Oral Solution - PA, NF
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Elyxyb (celecoxib) Oral Solution
Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of use: ELYXYB is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Elyxyb	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of migraine with or without aura	

AND

2 - Trial and failure, contraindication or intolerance to two of the following generics:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

Product Name: Elyxyb

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to two of the following generics:

- Almotriptan tablet
- Eletriptan tablet
- Frovatriptan tablet
- Naratriptan tablet
- Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)
- Sumatriptan tablet/nasal spray
- Zolmitriptan tablet/zolmitriptan ODT

3 . References

1. Elyxyb Prescribing Information. Dr. Reddy's Laboratories Limited. Telangana, India. May 2020.

Prior Authorization Guideline

Guideline Name	Emflaza (deflazacort) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Emflaza (deflazacort)
Duchenne muscular dystrophy (DMD) Indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 2 years of age and older.

2 . Criteria

Product Name: Emflaza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Duchenne muscular dystrophy (DMD)	

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - One of the following [A, 2]:

3.1 Documentation of a confirmed mutation of the dystrophin gene

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

7 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

Product Name: Emflaza

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength)</p> <p style="text-align: center;">AND</p> <p>2 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily</p>	

Product Name: Emflaza	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of Duchenne muscular dystrophy (DMD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]</p> <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following [A, 2]:</p> <p style="padding-left: 20px;">3.1 Documentation of a confirmed mutation of the dystrophin gene</p>	

OR

3.2 Muscle biopsy confirmed an absence of dystrophin protein

AND

4 - Patient is 2 years of age or older

AND

5 - Prescribed by or in consultation with a neurologist who has experience treating children

AND

6 - Patient has had a trial and failure or intolerance to prednisone or prednisolone given at a dose of 0.75 mg/kg/day or 10 mg/kg/weekend [B, 3-5]

AND

7 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

3 . Endnotes

- A. Genetic testing after a positive biopsy diagnosis of Duchenne muscular dystrophy (DMD) is mandatory [2]. However a muscle biopsy is not necessary if a positive genetic diagnosis is confirmed first. In rare cases, when a genetic test has been done but no mutation has been found, a muscle biopsy is the next necessary step for patients who have increased creatine kinase concentrations and symptoms consistent with DMD.
- B. Prednisone 0.75 mg/kg/d should be considered the optimal prednisone dose in DMD. Over 12 months, prednisone 10 mg/kg/weekend is equally effective, although long term outcomes of this alternative regimens are unknown [3].

4 . References

1. Emflaza Prescribing Information. PTC Therapeutics, Inc. South Plainfield, NJ. June 2021.
2. Bushby K, Finkel R, Birnkrant DJ, et al; DMD Care Considerations Working Group. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. *Lancet Neurol.* 2010;9(1):77-93.
3. Gloss D, Moxley RT 3rd, Ashwal S, Oskoui M. Practice guideline update summary: Corticosteroid treatment of Duchenne muscular dystrophy: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology.* 2016;86(5):465-72.
4. Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. *Neurology.* 2016 Nov 15;87(20):2123-2131.
5. FDA Center for Drug Evaluation and Research. Medical Review [Application Number 208684Orig1s000, 208685Orig1s000]. FDA Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000MedR.pdf. Accessed March 30, 2023.

Empaveli (pegcetacoplan)

Prior Authorization Guideline

Guideline Name	Empaveli (pegcetacoplan)
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Empaveli (pegcetacoplan)
Paroxysmal Nocturnal Hemoglobinuria Indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

2 . Criteria

Product Name: Empaveli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)	

Product Name: Empaveli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions)</p>	

3 . References

1. Empaveli Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. May 2021.
2. Per clinical consultation with specialist, June 18, 2021.
3. Kulasekararaj AG., et al. "Ravulizumab (ALXN1210) vs Eculizumab in C5-Inhibitor–Experienced Adult Patients with PNH: the 302 Study." *Blood*, vol. 133, no. 6, 2019, pp. 540–549.
4. Hillmen P, et al. "Pegcetacoplan versus Eculizumab in Paroxysmal Nocturnal Hemoglobinuria." *New England Journal of Medicine*, vol. 384, no. 11, 2021, pp. 1028–1037.

Prior Authorization Guideline

Guideline Name	Enbrel (etanercept)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Enbrel
<p>Rheumatoid Arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis. Enbrel can be initiated in combination with methotrexate (MTX) or used alone.</p> <p>Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients ages 2 and older.</p> <p>Psoriatic Arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with psoriatic arthritis. Enbrel can be used with or without MTX.</p> <p>Plaque Psoriasis (PsO) Indicated for the treatment of patients 4 years of age and older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.</p> <p>Ankylosing Spondylitis (AS) Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.</p>

2 . Criteria

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active rheumatoid arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none"> • methotrexate • leflunomide • sulfasalazine 	

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:</p> <ul style="list-style-type: none"> • leflunomide • methotrexate 	

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [5]:</p> <ul style="list-style-type: none">• Actively inflamed joints• Dactylitis• Enthesitis• Axial disease• Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Dermatologist• Rheumatologist	

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline • Reduction in the body surface area (BSA) involvement from baseline 	

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe chronic plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [6]:</p> <ul style="list-style-type: none"> • Greater than or equal to 3% body surface area involvement • Severe scalp psoriasis • Palmoplantar (i.e., palms, soles), facial, or genital involvement 	

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [7]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1, 6]:	
<ul style="list-style-type: none">• Reduction the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [8]

Product Name: Enbrel	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 8]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

3 . References

1. Enbrel Prescribing Information. Amgen. Thousand Oaks, CA. April 2021.

2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
6. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol* 2019;80:1029-72.
7. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021;84:432-70.
8. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.

Endari (L-glutamine oral powder)

Prior Authorization Guideline

Guideline Name	Endari (L-glutamine oral powder)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Endari (L-glutamine)
Sickle Cell Disease Indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

2 . Criteria

Product Name: Endari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of sickle cell disease	

AND

2 - Used to reduce acute complications of sickle cell disease

AND

3 - Patient is 5 years of age and older

Product Name: Endari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Endari Prescribing Information. Emmaus Medical, Inc. Torrance, CA. October 2020.

Prior Authorization Guideline

Guideline Name	Enspryng (satralizumab-mwge)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Enspryng (satralizumab-mwge)
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)	

AND

2 - Patient is anti-aquaporin-4 (AQP4) antibody positive

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Enspryng	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Enspryng Prescribing Information. Genentech, Inc. South San Francisco, CA. August 2020.

Prior Authorization Guideline

Guideline Name	Epclusa (sofosbuvir/velpatasvir) - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Epclusa (sofosbuvir and velpatasvir)
Chronic hepatitis C virus (HCV) Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes

*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis | Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6

Approval Length | 12 Week(s)

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis | Chronic Hepatitis C (without decompensation) - Genotype 1, 4, 5, or 6

Approval Length | 12 Week(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

5.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3</p> <p style="text-align: center;">AND</p> <p>2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]</p> <p style="text-align: center;">AND</p> <p>3 - Patient does NOT have decompensated liver disease (Child-Pugh Class B or C)</p>	

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 For continuation of prior brand sofosbuvir/velpatasvir

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2, 3
Approval Length	12 Week(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3	
AND	

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient does not have decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes	*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.
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Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Trial and failure or intolerance to ONE of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to **ONE** of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Eplclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - Trial and failure or intolerance to Brand Eplclusa, unless already receiving sofosbuvir/velpatasvir therapy

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Epclusa plus ribavirin
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Both of the following:

- Patient has decompensated liver disease (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

5 - One of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Epclusa*

Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
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Approval Length	24 Week(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of chronic hepatitis C virus genotype 1, 2, 3, 4, 5, or 6

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

Notes

*Approve brand Epclusa at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6	
AND	
2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]	

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Trial and failure or intolerance to ONE of the following:

- Brand Epclusa

- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 1, 4, 5, or 6</p> <p style="text-align: center;">AND</p> <p>2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has decompensated liver disease (Child-Pugh Class B or C)</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Patient is ribavirin intolerant or ineligible</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">4.2 Both of the following:</p> <p style="padding-left: 40px;">4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment</p>	

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to **ONE** of the following:

- Brand Epclusa
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Brand sofosbuvir/velpatasvir	
Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C virus genotype 2 or 3	
AND	

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - Trial and failure or intolerance to Brand Epclusa, unless already receiving sofosbuvir/velpatasvir therapy

Product Name: Brand sofosbuvir/velpatasvir

Diagnosis	Chronic Hepatitis C - Genotype 2, 3 - Patients with Decompensated Liver Disease - Ribavirin Intolerance/Ineligible OR Prior Sofosbuvir or NS5A-based Treatment Failure
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Approval Length	24 Week(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C virus genotype 2 or 3

AND

2 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

3 - Patient has decompensated liver disease (Child-Pugh Class B or C)

AND

4 - One of the following:

4.1 Patient is ribavirin intolerant or ineligible

OR

4.2 Both of the following:

4.2.1 Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based treatment

AND

4.2.2 Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to Brand Epclusa

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

3 . References

1. Epclusa Prescribing Information. Gilead Science, Inc. Foster City, CA. April 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Prior Authorization Guideline

Guideline Name	Epidiolex (cannabidiol)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Epidiolex (cannabidiol oral solution)
Lennox-Gastaut syndrome (LGS) Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 1 year of age and older.
Dravet syndrome (DS) Indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 1 year of age and older.
Tuberous sclerosis complex (TSC) Indicated for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients 1 year of age and older.

2 . Criteria

Product Name: Epidiolex	
Diagnosis	Lennox-Gastaut syndrome (LGS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS)

AND

2 - Trial of, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A-B]

AND

3 - Patient is 1 year of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex	
Diagnosis	Dravet syndrome (DS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of seizures associated with Dravet syndrome (DS)	
AND	
2 - Patient is 1 year of age or older	

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex

Diagnosis	Tuberous sclerosis complex
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of seizures associated with tuberous sclerosis complex (TSC)

AND

2 - Patient is 1 year of age or older

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Epidiolex

Diagnosis	Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), Tuberous sclerosis complex (TSC)
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

3 . Endnotes

- A. The effectiveness of Epidiolex for the treatment of seizures associated with LGS was established in two randomized, double-blind, placebo-controlled trials in patients aged 2 to 55 years. In study 2, 225 patients underwent randomization, of whom 76 were assigned to the 20-mg cannabidiol group, 73 to the 10-mg cannabidiol group, and 76 to the placebo group; Patients in each group had previously received a median of 6 antiepileptic drugs (range, 0 to 22), but the drugs had failed to control the seizures; the patients were receiving a median of 3 antiepileptic drugs concomitantly at the time of trial entry. [3]
- B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Epidiolex Prescribing Information. Greenwich Biosciences, Inc. Carlsbad, CA. April 2022.
2. Per clinical consult with neurologist, July 30, 2018.
3. Devinsky O, Patel AD, Cross JH, et al. Effect of cannabidiol on drop seizures in the Lennox-Gastaut syndrome. *N Engl J Med.* 2018 May 17;378(20):1888-1897.
4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. *Epilepsia.* 2010 Jun;51(6):1069-77.

Prior Authorization Guideline

Guideline Name	Ergot Alkaloids
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Guideline Note:

Effective Date:	5/1/2022
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1 . Indications

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection
<p>Migraine Indicated for the acute treatment of migraine headaches with or without aura.</p> <p>Cluster Headache Indicated for the acute treatment of cluster headache episodes.</p>
Drug Name: Migranal (dihydroergotamine mesylate) nasal spray
<p>Migraine Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.</p>
Drug Name: Cafergot (ergotamine tartrate and caffeine) tablet, Ergomar (ergotamine tartrate) sublingual tablet, Migergot (ergotamine tartrate and caffeine) suppository
<p>Headache Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called "histaminic cephalalgia".</p>
Drug Name: Trudhesa (dihydroergotamine mesylate) nasal spray
<p>Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: - Not indicated for the preventive treatment of migraine. - Not indicated for the management of hemiplegic or basilar migraine.</p>

2 . Criteria

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of migraine headaches with or without aura</p> <p style="text-align: center;">AND</p> <p>2 - Will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [A]</p> <p style="text-align: center;">AND</p> <p>4 - One of the following: [3]</p> <ul style="list-style-type: none"> • Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan) • Contraindication to all triptans <p style="text-align: center;">AND</p>	

5 - If patient has 4 or more headache days per month, patient must meet one of the following:
[B, 4]

5.1 Currently being treated with Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications

OR

5.2 Currently being treated with Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications

OR

5.3 Currently being treated with a beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications

OR

5.4 Currently being treated with Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

6 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafegot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray

Diagnosis	Migraines
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following specialists:</p> <ul style="list-style-type: none"> • Neurologist • Pain specialist • Headache specialist [C] 	

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cluster headache</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older [A]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to sumatriptan injection [5]</p>	

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafegot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository

Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

3 . Endnotes

- A. The safety and effectiveness in pediatric patients has not been established. [1, 2]
- B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence):

- antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [3, 4]
- C. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS) [6]

4 . References

1. D.H.E. 45 Prescribing Information. Valeant Pharmaceuticals North America LLC. Bridgewater, NJ. November 2019.
2. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. July 2019.
3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. *Headache*. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10;86(19):1818-26.
5. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016 Jul;56(7):1093-106.
6. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed September 28, 2021.
7. Cafergot Prescribing Information. Sandoz Inc. Princeton, NJ. May 2018
8. Ergomar Prescribing Information. TerSera Therapeutics LLC. Deerfield, IL. February 2020.
9. Migergot Prescribing Information. Cosette Pharmaceuticals, Inc.. South Plainfield, NJ. July 2019.
10. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.

Erivedge (vismodegib)

Prior Authorization Guideline

Guideline Name	Erivedge (vismodegib)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Erivedge (vismodegib)
Basal cell carcinoma Indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 . Criteria

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of metastatic basal cell carcinoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of locally advanced basal cell carcinoma

AND

1.2.2 One of the following:

- Disease recurred following surgery
- Patient is not a candidate for both surgery and radiation

AND

2 - Prescribed by or in consultation with one of the following [3]:

- Dermatologist
- Oncologist

Product Name: Erivedge	
Diagnosis	Basal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Erivedge Prescribing Information. Genentech USA Inc. South San Francisco, CA. August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 4, 2020..
3. Per clinical consult with oncologist, February 24, 2011.

Erleada (apalutamide)

Prior Authorization Guideline

Guideline Name	Erleada (apalutamide)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Erleada (apalutamide)
Non-metastatic castration-resistant prostate cancer Indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).
Drug Name: Erleada (apalutamide)
Metastatic castration-sensitive prostate cancer Indicated for the treatment of patients with metastatic, castration-sensitive prostate cancer (M-CSPC).

2 . Criteria

Product Name: Erleada	
Diagnosis	Castration-resistant (prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer (CRPC)

AND

2 - Prescribed by or in consultation with an oncologist or urologist

Product Name: Erleada	
Diagnosis	Castration-sensitive prostate cancer (CSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of castration sensitive prostate cancer (CSPC)	
AND	
2 - Prescribed by or in consultation with an oncologist or urologist	

Product Name: Erleada	
Diagnosis	Castration-resistant prostate cancer (CRPC), Castration sensitive prostate cancer (CSPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of disease progression while on therapy

3 . References

1. Erleada prescribing information. Janssen Ortho LLC. Gurabo, PR. February 2023.
2. Klotz L, O'Callaghan C, Ding K, et al. Nadir testosterone within first year of androgen-deprivation therapy (ADT) predicts for time to castration-resistant progression: a secondary analysis of the PR-7 trial of intermittent versus continuous ADT. *J Clin Oncol* 2015;33:1151-56. doi:10.1200/JCO.2014.58.2973.

Prior Authorization Guideline

Guideline Name	Erythropoietic Agents
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
<p>Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD) including patients on dialysis and patients not on dialysis.</p> <p>Anemia in Cancer Patients on Chemotherapy Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. Indicated for treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Aranesp has not been shown to improve quality of life, fatigue, or patient well-being. Aranesp is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; and (4) As a substitute for red blood cell (RBC) transfusions in</p>

patients who require immediate correction of anemia.

Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS) Have been used for the treatment of anemia in patients with MDS. [20]

Drug Name: Epogen (epoetin alfa), Procrit (epoetin alfa), and Retacrit (epoetin alfa-epbx)

Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion.

Anemia Due to Zidovudine in HIV-infected Patients Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of less than or equal to 500 mUnits/mL.

Anemia Due to Chemotherapy in Patients with Cancer Indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and upon initiation, there is a minimum of 2 additional months of planned chemotherapy. Limitations of Use: Epoetin alfa has not been shown to improve quality of life, fatigue, or patient well-being. Epoetin alfa is not indicated for use: (1) In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy; (2) In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure; (3) In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion; (4) As a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia.

Reduction of Allogeneic Red Blood Cell Transfusions in Patients Undergoing Elective, Noncardiac, Nonvascular Surgery Indicated to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin greater than 10 to less than or equal to 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery. Epogen, Retacrit, and Procrit are not indicated for patients who are willing to donate autologous blood preoperatively. Limitations of Use: Epogen and Procrit have not been shown to improve quality of life, fatigue, or patient well-being. Epogen and Procrit are not indicated for use: (1) In patients scheduled for surgery who are willing to donate autologous blood; (2) In patients undergoing cardiac or vascular surgery.

Off Label Uses: Anemia associated with HIV infection Have been used for the treatment of anemia associated with HIV infection in patients not receiving zidovudine. [5]

Anemia in Hepatitis C virus (HCV) infected patients due to combination therapy of ribavirin and interferon or peg-interferon Have been used for the treatment of anemia in patients with hepatitis C virus (HCV) infection who are being treated with the combination of ribavirin and interferon or peginterferon alfa. [20]

Anemia in patients with Myelodysplastic Syndrome (MDS) Have been used for the treatment of anemia in patients with MDS. [5, 20]

Drug Name: Mircera (methoxy polyethylene glycol-epoetin beta)

Anemia Due to Chronic Kidney Disease Indicated for the treatment of anemia associated with chronic kidney disease (CKD) in: (1) adult patients on dialysis and adult patients not on dialysis; (2) pediatric patients 5 to 17 years of age on hemodialysis who are converting from another ESA after their hemoglobin level was stabilized with an ESA. Mircera is not indicated and is not recommended: (1) In the treatment of anemia due to cancer chemotherapy; or (2) As a substitute for RBC transfusions in patients who require immediate correction of anemia. Mircera has not been shown to improve symptoms, physical functioning or health-related quality of life.

2 . Criteria

Product Name: Aranesp, Epogen, Procrit, or Retacrit*	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic kidney disease (CKD)</p> <p style="text-align: center;">AND</p> <p>2 - Verification of iron evaluation for adequate iron stores^ [A, J]</p> <p style="text-align: center;">AND</p> <p>3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [1, 3, 9, 13-17, 29, 33, B]</p> <ul style="list-style-type: none">• Hematocrit (Hct) < 30%• Hemoglobin (Hgb) < 10g/dL	

AND

4 - One of the following: [1, 3, 33, L]

4.1 Patient is on dialysis

OR

4.2 All of the following:

4.2.1 Patient is NOT on dialysis

AND

4.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

4.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.
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Product Name: Mircera*	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic kidney disease (CKD)	

AND

2 - Verification of iron evaluation for adequate iron stores[^] [A, J]

AND

3 - One of the following:

3.1 All of the following:

3.1.1 Patient is greater than or equal to 18 years of age

AND

3.1.2 Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [9, 13-17, 29, 31, B]

- Hematocrit (Hct) < 30%
- Hemoglobin (Hgb) < 10 g/dL

AND

3.1.3 One of the following: [31]

3.1.3.1 Patient is on dialysis

OR

3.1.3.2 All of the following:

3.1.3.2.1 Patient is NOT on dialysis

AND

3.1.3.2.2 The rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion

AND

3.1.3.2.3 Reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal

OR

3.2 All of the following:

3.2.1 Patient is between 5 and 17 years of age

AND

3.2.2 Patient is on hemodialysis

AND

3.2.3 Patient's hemoglobin level has been stabilized by treatment with another erythropoietin stimulating agent (ESA) (e.g., Aranesp, Procrit)

AND

3.2.4 Patient is converting to Mircera from another ESA (e.g., Aranesp, Procrit)

Notes

^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Aranesp, Epogen, Mircera*, Procrit, or Retacrit*	
Diagnosis	Anemia due to CKD
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - One of the following:

2.1 Both of the following:

- Patient is on dialysis
- Most recent or average Hct over 3 months is 33% or less (Hgb 11 g/dL or less)

OR

2.2 Both of the following:

- Patient is not on dialysis
- Most recent or average (avg) Hct over 3 mo is 30% or less (Hgb 10 g/dL or less)

OR

2.3 Both of the following:

- Request is for a pediatric patient
- Most recent or average Hct over 3 mo is 36% or less (Hgb 12 g/dL or less)

AND

3 - One of the following: [1-3, 35, 37]

3.1 Decrease in the need for blood transfusion

OR

3.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level

AND

4 - Verification of iron evaluation for adequate iron stores[^] [A, J]

Notes

[^]Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Epogen, Procrit, or Retacrit*

Diagnosis Anemia in HIV-infected patients

Approval Length 6 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Verification of iron evaluation for adequate iron stores[^] [2-3, 33]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request:

- Hemoglobin (Hgb) < 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) < 36%

AND

3 - Serum erythropoietin level less than or equal to 500 mU/mL [2-3, 24, 26, 33]

AND

4 - One of the following:

<ul style="list-style-type: none"> • Patient is receiving zidovudine therapy [2-3, 33] • Diagnosis of HIV infection [off-label] [5, 11, 24-28] 	
Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Epogen, Procrit, or Retacrit*	
Diagnosis	Anemia in HIV-infected patients
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Verification of anemia as defined by one of the following: [2, 3, 33]</p> <ul style="list-style-type: none"> • Most recent or average hematocrit (Hct) over a 3-month period was below 36% • Most recent or average hemoglobin (Hgb) over a 3-month period was below 12 g/dL <p style="text-align: center;">AND</p> <p>2 - One of the following: [2, 3, 33]</p> <p>2.1 Decrease in the need for blood transfusion</p> <p style="text-align: center;">OR</p> <p>2.2 Hemoglobin (Hgb) increased greater than or equal to 1g/dL from pre-treatment level</p>	
Notes	*Product may be excluded depending on the plan.

Product Name: Aranesp, Epogen, Procrit, or Retacrit*	
Diagnosis	Anemia in cancer patients on chemotherapy
Approval Length	3 month [C]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Verification that other causes of anemia have been ruled out [1, 3, 33, M]</p> <p style="text-align: center;">AND</p> <p>2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1, 3]</p> <ul style="list-style-type: none"> • Hematocrit (Hct) < 30% • Hemoglobin (Hgb) < 10 g/dL [N] <p style="text-align: center;">AND</p> <p>3 - Verification of iron evaluation for adequate iron stores^ [1-3, 8, 33, G]</p> <p style="text-align: center;">AND</p> <p>4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]</p> <p style="text-align: center;">AND</p> <p>5 - Patient is receiving chemotherapy [1-3, 33, D]</p>	
Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Aranesp, Epogen*, Procrit, or Retacrit*	
Diagnosis	Anemia in cancer patients on chemotherapy
Approval Length	3 Month [C]
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]</p> <ul style="list-style-type: none"> • Hemoglobin (Hgb) < 10 g/dL • Hematocrit (Hct) < 30% [10, 18-19] <p style="text-align: center;">AND</p> <p>2 - One of the following: [1-3, 33]</p> <p>2.1 Decrease in the need for blood transfusion</p> <p style="text-align: center;">OR</p> <p>2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level</p> <p style="text-align: center;">AND</p> <p>3 - Patient is receiving chemotherapy [D]</p>	
Notes	*Product may be excluded depending on the plan.

Product Name: Epogen, Procrit, or Retacrit*	
Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery

AND

2 - Hemoglobin (Hgb) is greater than 10 to less than or equal to 13 g/dL

AND

3 - Patient is at high risk for perioperative transfusions

AND

4 - Patient is unwilling or unable to donate autologous blood pre-operatively

AND

5 - Verification of iron evaluation for adequate iron stores[^] [2-3, 33]

Notes

[^]Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Aranesp, Epogen, Procrit, or Retacrit*

Diagnosis | Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]

Approval Length | 3 months [I]

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietic level less than or equal to 500 mU/mL
- Diagnosis of transfusion-dependent MDS

AND

3 - Verification of iron evaluation for adequate iron stores[^] [4, A, H]

Notes	[^] Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.
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Product Name: Aranesp*, Epogen*, Procrit, or Retacrit	
Diagnosis	Anemia in MDS patients (off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Verification of anemia as defined by one of the following: [4, E]	
<ul style="list-style-type: none">• Most recent or average hematocrit (Hct) over a 3-month period was less than or equal to 36%• Most recent or average hemoglobin (Hgb) over a 3-month period was less than or equal to 12 g/dL	
AND	
2 - One of the following: [1-3, 33]	
2.1 Decrease in the need for blood transfusion	

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Notes

*Product may be excluded depending on the plan.

Product Name: Epogen, Procrit or Retacrit*

Diagnosis

Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]

Approval Length

3 month(s)

Therapy Stage

Initial Authorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of hepatitis C viral (HCV) infection [12, 20]

AND

2 - Verification of iron evaluation for adequate iron stores^ [2-3, 33]

AND

3 - Verification of anemia as defined by one of the following laboratory values collected within 30 days of the request: [P]

- Hematocrit (Hct) < 36%
- Hemoglobin (Hgb) < 12 g/dL

AND

4 - Verification of both of the following:

4.1 Patient is receiving ribavirin

AND

4.2 Patient is receiving one of the following:

- interferon alfa-2b
- interferon alfacon-1
- peginterferon alfa-2b
- peginterferon alfa-2a

Notes

^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores. *Product may be excluded depending on the plan.

Product Name: Epogen*, Procrit, or Retacrit*

Diagnosis Anemia due to HCV therapy

Approval Length 3 Months or if patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy.

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Verification of anemia as defined by one of the following: [35]

- Most recent or average hematocrit (Hct) over a 3-month period was 36% or less
- Most recent or average hemoglobin (Hgb) over a 3-month period was 12 g/dL or less

AND

2 - One of the following: [2, 3, 33]

2.1 Decrease in the need for blood transfusion

OR

2.2 Hemoglobin (Hgb) increased greater than or equal to 1 g/dL from pre-treatment level

Notes	*Product may be excluded depending on the plan.
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Product Name: Aranesp, Epogen, Mircera*, Procrit, or Retacrit*	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Off-label guideline approval criteria have been met[^]</p> <p style="text-align: center;">AND</p> <p>2 - Off-label requests other than those listed above for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [1-3, 31, 33]</p>	
Notes	[^] Off-label requests will be evaluated on a case-by-case basis by a clinical pharmacist. *Product may be excluded depending on the plan.

Product Name: Mircera	
Diagnosis	Off-Label Uses
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Off-label requests for Mircera will be evaluated on a case-by-case basis by a clinical pharmacist</p> <p style="text-align: center;">AND</p> <p>2 - Requests for coverage in patients with Hgb greater than 10 g/dL or Hct greater than 30% will not be approved [35]</p>	

3 . Endnotes

- A. Aranesp, Epogen, Mircera, Procrit, and Retacrit Prescribing Information recommend prior and during therapy, the patient's iron stores should be evaluated. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%. The majority of patients with CKD will require supplemental iron during the course of ESA therapy. [1-3, 31, 33]
- B. Aranesp, Epogen, Mircera, Procrit, or Retacrit Prescribing Information states that dialysis, and non-dialysis patients with symptomatic anemia considered for therapy should have a Hgb < 10 g/dL. [1-3, 31, 33]
- C. ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen. [18]
- D. ESAs are not indicated for patients receiving myelosuppressive therapy when the anticipated outcome is cure. [1-3, 33]
- E. NCCN panel recommends MDS patients aim for a target hgb level of less than or equal to 12 g/dL. [4]
- F. The American Cancer Society definition of "non-myeloid malignancy" is any malignancy that is not a myeloid leukemia. Non-myeloid cancers include all types of carcinoma, all types of sarcoma, melanoma, lymphomas, lymphocytic leukemias (ALL and CLL), and multiple myeloma. [30]
- G. Absolute iron deficiency is defined as ferritin <30 ng/mL and TSAT <20%. Functional iron deficiency in patients receiving ESAs is defined as ferritin 30-800 ng/mL and TSAT 20%-50%. No iron deficiency is defined as ferritin >800 ng/mL or TSAT greater or equal to 50%. [8]
- H. Iron repletion needs to be verified before instituting Epo therapy. [4]
- I. Detection of erythroid responses generally occurs within 6 to 8 weeks of treatment. If no response occurs in this time frame, this treatment should be considered a failure and discontinued. [4]
- J. Iron stores evaluation is recommended to occur every month during initial erythropoietin treatment in adults with chronic kidney disease or at least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an erythropoietin. [7]
- K. Anemia in HIV patients has been defined as hemoglobin less than 10 g/dL [11, 25-26], hemoglobin less than 11 g/dL [11, 27], or hemoglobin less than 12 g/dL. [17]
- L. Although primarily used in patients with ESRD, ESAs such as erythropoietin and darbepoetin alfa also correct the anemia in those with CKD who do not yet require dialysis. [21, 32]
- M. Examples of other anemias include: vitamin B12, folate or iron deficiency anemia, hemolysis, or gastrointestinal bleeding.
- N. Data from a systematic review by the Agency for Healthcare Research and Quality (AHRQ) determined that delaying ESA treatment until hemoglobin is less than 10 g/dL resulted in fewer thromboembolic events and a reduced mortality. [8]
- O. Per consult with hematologist/oncologist, if a patient does not respond to one short-acting ESA, switching to another short-acting agent would not provide any added benefit; instead, one would increase the dose or perhaps switch to a long-acting agent. [34]
- P. Epoetin alfa was effective in maintaining the dose of ribavirin in anemic patients with chronic hepatitis C virus in patients with a baseline hemoglobin of 12 g/dL or less. [20]

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Evrysdi (risdiplam)

Prior Authorization Guideline

Guideline Name	Evrysdi (risdiplam)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Evrysdi (risdiplam)
Spinal Muscular Atrophy Indicated for the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients.

2 . Criteria

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of spinal muscular atrophy (SMA) Type I, II, or III [1-3, A]

AND

2 - Both of the following: [1-7]

2.1 The mutation or deletion of genes in chromosome 5q resulting in one of the following: [B]

2.1.1 Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13)

OR

2.1.2 Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2])

AND

2.2 Patient has at least 2 copies of SMN2 [C]

AND

3 - Patient is not dependent on invasive ventilation or tracheostomy [2-3, D]

AND

4 - Patient is not dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

5 - At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability*: [2-7, E]

- Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood)
- Hammersmith Functional Motor Scale Expanded (HF MSE)

- Revised Upper Limb Module (RULM) Test (Non ambulatory)
- Children’s Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
- Motor Function Measure 32 (MFM-32) Scale
- Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III)

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

7 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

8 - One of the following: [2-3, 10, F]

8.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

8.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

Notes

*Baseline assessments for patients less than 2 months of age requesting risdiplam are not necessary in order to not delay access to initial therapy in recently diagnosed infants. Initial assessments shortly post-therapy can serve as baseline with respect to efficacy reauthorization assessment.

Product Name: Evrysdi	
Diagnosis	Spinal Muscular Atrophy
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy from pretreatment baseline status as demonstrated by the most recent results from one of the following exams:

1.1 One of the following HINE-2 milestones: [2]

- Improvement or maintenance of previous improvement of at least a 2 point (or maximal score) increase in ability to kick
- Improvement or maintenance of previous improvement of at least a 1 point increase in any other HINE-2 milestone (e.g., head control, rolling, sitting, crawling, etc.), excluding voluntary grasp
- Patient exhibited improvement, or maintenance of previous improvement in more HINE motor milestones than worsening, from pretreatment baseline (net positive improvement)
- Patient has achieved and maintained any new motor milestones when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.2 One of the following HFMSE milestones: [8]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.3 One of the following RULM test milestones: [2, 8-9]

- Improvement or maintenance of a previous improvement of at least a 2 point increase in score from pretreatment baseline

- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.4 One of the following CHOP INTEND milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 4 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.5 One of the following MFM-32 milestones: [2]

- Improvement or maintenance of a previous improvement of at least a 3 point increase in score from pretreatment baseline
- Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to do so (e.g., sit unassisted, stand, walk)

OR

1.6 Improvement in the ability to sit without support for at least 5 seconds as assessed by item 22 of the Gross Motor Scale of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III) [2-3]

AND

2 - Patient continues to not be dependent on invasive ventilation or tracheostomy [2-3, D]

AND

3 - Patient continues to not be dependent on the use of non-invasive ventilation beyond use for naps and nighttime sleep [3, D]

AND

4 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA

AND

5 - Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza) [2-3, 10, F]

AND

6 - One of the following: [2-3, 10, F]

6.1 Patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma)

OR

6.2 Both of the following:

- Patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma)
- Documentation of inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months)

3 . Endnotes

- A. There were two major Phase 2/3 trials that the FDA assessed when determining Evrysdi's clinical efficacy and subsequent approval (SUNFISH and FIREFISH). SUNFISH only enrolled patients with SMA Types 2 and 3 and FIREFISH only enrolled patients with SMA Type 1. [2-3]
- B. This is the definition that the clinical trials SUNFISH and FIREFISH used. Also consistent with clinical guidelines. [2-7]
- C. FIREFISH required patients to have 2 copies of SMN2, and SUNFISH only enrolled patients with 2-4 copies of SMN2. [2-3]

- D. Invasive ventilation or tracheostomy was an exclusion criteria in both the SUNFISH and FIREFISH trials. Use of non-invasive ventilation beyond use for naps and nighttime sleep was only an exclusion criteria in FIREFISH. [2-3]
- E. MFM-32 was included in Evrysdi criteria but not Spinraza because Spinraza did not study MFM-32 as an endpoint. Baseline motor score standards was only used as an inclusion criterion for SUNFISH. Revised upper limb module (RULM) entry item A (Brooke score) equal to or greater than 2 AND MFM-32 (Item 9) scores equal to or greater than 1 were required. As this was only for the SUNFISH trial and only applied to some of the motor scores, it was deemed unnecessary to include as a criterion. [2]
- F. A recent European ad-hoc consensus statement on SMA stated that there currently is no published evidence that the combination of two disease modifying therapies (e.g., Evrysdi and Zolgensma) is superior to any single treatment alone. Both FIREFISH and SUNFISH excluded patients that were on concomitant or previous treatment with either SMN2-targeting antisense oligonucleotide, or gene therapy (e.g., Spinraza or Zolgensma). JEWELFISH is an ongoing open label phase 2 trial that included patients previously treated with another SMA targeted therapy (e.g., Zolgensma, Spinraza). JEWELFISH is scheduled to be completed in January 2025. [2-3,10-11]

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Evusheld (tixagevimab and cilgavimab)

Prior Authorization Guideline

Guideline Name	Evusheld (tixagevimab and cilgavimab)
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Evusheld (tixagevimab co-packaged with cilgavimab) injection
Pre-exposure prophylaxis coronavirus disease 2019 (COVID-19) Emergency Use Authorization (EUA) for the product Evusheld for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg). Limitations of use: Not authorized for use in individuals for treatment of COVID-19 or post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. Pre-exposure prophylaxis with Evusheld is not a substitute for vaccination in individuals whom COVID-19 vaccination is recommended. In individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination.

2 . Criteria

Product Name: Evusheld	
Approval Length	6 Month(s) [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19)

AND

2 - Patient is 12 years of age or older

AND

3 - Patient weighs at least 40 kg

AND

4 - Both of the following:

- Patient is not currently infected with SARS-COV-2
- Patient has not had a known recent exposure to an individual infected with SARS-COV-2

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Patient is moderately to severe immune compromised due to a medical condition or receipt of immunosuppressive medications or treatments [A, 1]

AND

5.1.2 Patient may not mount to an adequate immune response to COVID-19 vaccination

OR

5.2 Patient is unable to complete the COVID-19 vaccine series due to a severe adverse reaction (e.g., difficulty breathing or wheezing, swelling of the tongue or throat) to the COVID-19 vaccine(s) and/or COVID-19 vaccine component(s) [2]

3 . Endnotes

- A. Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate response to COVID-19 vaccination: 1) Active treatment for solid tumor and hematologic malignancies. 2) Receipts of solid-organ transplant and taking immunosuppressive therapy. 3) Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy). 4) Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome). 5) Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV). 6) Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents). [1]
- B. Longer term data from the study PROVENT indicate that Evusheld may be effective for pre-exposure prophylaxis for 6 months post-administration. [1]

4 . References

1. Evusheld Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. December 2021.
2. CDC. COVID-19 and Your Health. Centers for Disease Control and Prevention. Published February 11, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html>

Exkivity (mobocertinib)

Prior Authorization Guideline

Guideline Name	Exkivity (mobocertinib)
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Guideline Note:

Effective Date:	5/1/2022
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1 . Indications

Drug Name: Exkivity (mobocertinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Exkivity	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Disease is epidermal growth factor receptor (EGFR) exon 20 insertion mutation positive as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has progressed on or following prior treatment with a platinum-containing regimen (e.g., carboplatin, cisplatin)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Exkivity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Exkivity Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. September 2021.

Prior Authorization Guideline

Guideline Name	Extended Release Tramadol Products
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: ConZip, tramadol ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of moderate to moderately severe chronic pain AND 2 - Trial and failure (of a minimum 30 day supply) or intolerance to an immediate release tramadol containing product [e.g., Ultram (tramadol), Ultracet (tramadol/acetaminophen)]	

2 . References

1. Conzip prescribing information. Vectical Pharmaceuticals, LLC. Bridgewater, NJ. October 2019.
2. Tramadol Extended Release prescribing information. Lupin Pharmaceuticals, Inc. Baltimore, MD. May 2019.

Eysuvis (loteprednol etabonate ophthalmic suspension)

Prior Authorization Guideline

Guideline Name	Eysuvis (loteprednol etabonate ophthalmic suspension)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Eysuvis (loteprednol etabonate ophthalmic suspension)
Dry eye disease (DED) Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of dry eye disease

AND

2 - Trial and failure for a minimum 14 days duration of therapy, contraindication, or intolerance to one of the following:

- 0.5% loteprednol suspension
- 0.1% fluorometholone suspension

AND

3 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., improvement in dry eye symptoms)	
AND	
2 - Prescribed by or in consultation with one of the following:	
<ul style="list-style-type: none">• Ophthalmologist• Optometrist	

3 . References

1. Eysuvis prescribing information. Kala Pharmaceuticals, Inc. Watertown, MA. November 2020.
2. Per clinical consult with ophthalmologist, December 21, 2020.
3. Shtein, RM. Dry eye disease. In: Post T, ed. UpToDate. UpToDate; 2020. Accessed December 16, 2020. www.uptodate.com
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: <https://www.micromedexsolutions.com/>. Accessed December 16, 2020.

Farydak (panobinostat)

Prior Authorization Guideline

Guideline Name	Farydak (panobinostat)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Farydak	
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of multiple myeloma AND 2 - Used in combination with both of the following [3]: <ul style="list-style-type: none">• Velcade (bortezomib)	

<ul style="list-style-type: none"> Dexamethasone <p style="text-align: center;">AND</p> <p>3 - Patient has received at least two prior treatment regimens which included both of the following: [1]*</p> <ul style="list-style-type: none"> Velcade (bortezomib) Immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)] <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist/hematologist</p>	
Notes	*The concomittant use of Velcade and an immunomodulatory agent c onstitutes as one of two required prior treatment regimens.

Product Name: Farydak	
Approval Length	12 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on Farydak therapy</p>	

2 . References

- Farydak Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2016.
- San-Miguel JF, Hungria VT, Yoon SS, et al. Panobinostat plus bortezomib and dexamethasone versus placebo plus bortezomib and dexamethasone in patients with relapsed or relapsed and refractory multiple myeloma: a multicentre, randomised, double-blind phase 3 trial. *Lancet Oncol.* 2014;15(11):1195-206.
- National Comprehensive Cancer Network (NCCN), Clinical Practice Guidelines in Oncology. Multiple Myeloma. v4.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed July 9, 2018.

Fasenra (benralizumab)

Prior Authorization Guideline

Guideline Name	Fasenra (benralizumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Fasenra (benralizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Limitations of use: Fasenra is not indicated for treatment of other eosinophilic conditions. Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Fasenra	
Approval Length	6 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of severe asthma

AND

2 - Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter [6, C, G]

AND

3 - One of the following:

3.1 Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2, 3, C]

OR

3.2 Prior asthma-related hospitalization within the past 12 months [D]

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following [4, 5, A, B]:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Patient is 12 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Fasenra

Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

3 . Background

Clinical Practice Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [5]

Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

This is not a table of equivalence, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply

potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

- A. The American Thoracic Society (ATS) defines severe asthma as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy. In patients greater than 6 years of age, "Gold Standard/International Guidelines treatment" is high dose ICS plus a long acting beta-2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy [4].
- B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [5]
- C. The SIROCCO and CALIMA trials evaluated the effect of benralizumab 30mg administered in 4 week and 8 week regimens as add on therapy to standard of care medicine. The trials enrolled patients 12 to 75 years of age with severe asthma defined as a history of two or more exacerbations in the previous year which needed systemic corticosteroids or a temporary increase in the patient's usual maintenance dose of oral corticosteroids. Patients were also required to have received treatment with a medium dose or high dose ICS plus LABA for at least one year before enrollment. Both trials confirmed benralizumab significantly reduced the annual exacerbation rates and was generally well tolerated in patients who were uncontrolled on high dose ICS plus LABA and had a baseline blood eosinophil count of 300 cells per microliter or greater [2, 3]. The baseline eosinophil level requirement of greater than or equal to 150 cells per microliter and the requirement for a history of one or more exacerbations listed in the criteria comes from the inclusion criteria allowed in the ZONDA trial. The ZONDA trial was a 28-week, Phase 3, randomized, double blind, placebo controlled, multicenter, oral corticosteroid reduction trial [6].
- D. Recommendation inferred from the national P&T committee meeting, December 2015, regarding similar agent first-in-class IL-5 antagonist Nucala (mepolizumab) in the use of severe eosinophilic asthma.
- E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However, the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence, and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [5].

- F. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [5]
- G. The Institute for Clinical and Economic Review (ICER) defines eosinophilic inflammation as a blood eosinophil level greater than or equal to 150 cells per microliter at initiation of therapy. This is the lowest measured threshold for eosinophilic asthma in pivotal trials. [7]

5 . References

1. Fasenna Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. February 2021.
2. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2016 Oct 29;388(10056):2128-2141.
3. Bleecker ER, FitzGerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting Beta two agonist (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. *Lancet*. 2016 Oct 29;388(10056):2115-2127.
4. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
5. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
6. Nair P, Wenzel S, Rabe KF, et al. ZONDA Trial Investigators. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med*. 2017;376(25):2448-2458.
7. Institute for Clinical and Economic Review (ICER). Biologic therapies for treatment of asthma associated with type 2 inflammation: effectiveness, value, and value-based price benchmarks. https://icer.org/wp-content/uploads/2020/10/ICER_Asthma-Final-Report_Unredacted_08122020.pdf. Published December 20, 2018. Accessed April 15, 2022.

Prior Authorization Guideline

Guideline Name	Fecal Microbiota Agents - PA, NF
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Rebyota (fecal microbiota, live-jslm) suspension
Recurrent Clostridioides difficile infection (CDI) Indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Limitations of use: Rebyota is not indicated for treatment of CDI.
Drug Name: Vowst (fecal microbiota spores, live-brpk) capsule
Recurrent Clostridioides difficile infection (CDI) Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Limitations of use: Vowst is not indicated for treatment of CDI.

2 . Criteria

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Product Name: Rebyota	
Approval Length	14 Day(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:</p> <ul style="list-style-type: none"> • Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days • A positive stool test for C.difficile toxin or toxigenic C.difficile <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a history of one or more recurrent episodes of CDI</p> <p style="text-align: center;">AND</p> <p>4 - Both of the following:</p> <p>4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:</p> <ul style="list-style-type: none"> • oral vancomycin • Difucid (fidaxomicin) 	

AND

4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:</p> <ul style="list-style-type: none">• Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days• A positive stool test for C.difficile toxin or toxigenic C.difficile <p>AND</p> <p>2 - Patient is 18 years of age or older</p> <p>AND</p> <p>3 - Patient has a history of two or more recurrent episodes of CDI within 12 months</p>	

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

5 - Prescribed by or in consultation with one of the following:

- Gastroenterologist
- Infectious disease specialist

3 . Endnotes

- A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]

4 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.
2. Vowst Prescribing Information. Aimmune Therapeutics, Inc. Brisbane, CA. April 2023.
3. Per clinical consult with gastroenterologist, May 3, 2023.

Ferriprox (deferiprone)

Prior Authorization Guideline

Guideline Name	Ferriprox (deferiprone)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Ferriprox (deferiprone) Tablets
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.
Drug Name: Ferriprox (deferiprone) Oral Solution
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.

2 . Criteria

Product Name: Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - One of the following:

2.1 For Ferriprox oral solution, patient is 3 years of age or older

OR

2.2 For generic deferiprone tablet, patient is 8 years of age or older

AND

3 - One of the following:

3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin > 2,500 mcg/L, to one of the following chelation therapy: [A]

- Generic deferoxamine
- Generic deferasirox

OR

3.2 History of contraindication or intolerance to one of the following chelation therapy:

- Generic deferoxamine
- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$

Product Name: Brand Ferriprox tablet

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - Patient is 8 years of age or older

AND

3 - One of the following:

3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin $> 2,500$ mcg/L, to one of the following chelation therapy: [A]

- Generic deferoxamine
- Generic deferasirox

OR

3.2 History of contraindication or intolerance to one of the following chelation therapy:

- Generic deferoxamine
- Generic deferasirox

AND	
4 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$	
AND	
5 - Trial and failure, or intolerance to generic deferiprone tablets*	
Notes	*Product may require prior authorization

Product Name: Brand Ferriprox tablet, Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline</p> <p style="text-align: center;">AND</p> <p>2 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$</p>	

3 . Endnotes

- A. Failure to prior chelation therapy is defined as serum ferritin > 2,500 mcg/L. [1]

4 . References

1. Ferriprox tablets prescribing information. Apotex Inc., Toronto, Canada. November 2021.
2. Ferriprox solution prescribing information. Apotex Inc., Toronto, Canada. August 2021.

3. Deferiprone prescribing information. Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel. November 2022.

Prior Authorization Guideline

Guideline Name	Filspari (sparsentan)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Filspari (sparsentan)
Primary immunoglobulin A nephropathy (IgAN) Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

2 . Criteria

Product Name: Filspari	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Patient has an estimated glomerular filtration rate (eGFR) of greater than or equal to 30 mL/min/1.73 m²

AND

5 - Patient has been on a minimum 90-day trial of a maximally tolerated dose of one of the following:

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

AND

6 - Medication will not be used in combination with any of the following:

- Angiotensin receptor blocker or angiotensin receptor-neprilysin inhibitor
- Endothelin receptor antagonists (ERAs) [e.g., Letairis (ambrisentan), Tracleer (bosentan), Opsumit (macitentan)]

- Tekturna (aliskiren)

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name: Filispari	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates a positive clinical response to therapy as demonstrated by a decrease in urine protein-to-creatinine ratio (UPCR) from baseline</p> <p style="text-align: center;">AND</p> <p>2 - Medication is not taken in combination with any of the following:</p> <ul style="list-style-type: none"> • Angiotensin receptor blocker or angiotensin receptor-neprilysin inhibitor • Endothelin receptor antagonists (ERAs) [e.g., Letairis (ambrisentan), Tracleer (bosentan), Opsumit (macitentan)] • Tekturna (aliskiren) 	

3 . Endnotes

- A. IgAN can only be diagnosed with a kidney biopsy. [2]
- B. The International IgAN Prediction Tool incorporates clinical information at the time of biopsy and is a valuable resource to quantify risk of progression and inform shared decision-making with patients. [2]
- C. Patients who remain at high risk of progressive CKD despite maximal supportive care should be considered for a 6-month course of glucocorticoid therapy. The important risk of treatment-emergent toxicity must be discussed with patients, particularly those who have an eGFR <50 ml/min per 1.73 m². [2]

4 . References

1. Filspari Package Insert. Traverre Therapeutics, Inc. San Diego, CA. February 2023.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021;100(4S):S1-S276.

Finacea (azelaic acid)

Prior Authorization Guideline

Guideline Name	Finacea (azelaic acid)
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Guideline Note:

Effective Date:	3/1/2022
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1 . Criteria

Product Name: Finacea	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria 1 - Trial and failure, contraindication, or intolerance to metronidazole AND 2 - Trial and failure, contraindication, or intolerance to generic azelaic acid gel (Applies to brand Finacea only)	

Fintepla (fenfluramine)

Prior Authorization Guideline

Guideline Name	Fintepla (fenfluramine)
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Fintepla (fenfluramine)
Dravet Syndrome Indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.
Lennox-Gastaut Syndrome Indicated for the treatment of seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.

2 . Criteria

Product Name: Fintepla	
Diagnosis	Dravet Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of seizures associated with Dravet syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Trial and failure, contraindication or intolerance to one of the following:

- valproic acid
- clobazam

AND

3.1.2 Trial and failure, contraindication or intolerance to one of the following:

- Diacomit (stiripentol)
- Epidiolex (cannabidiol)
- topiramate
- zonisamide
- levetiracetam
- Briviact (brivaracetam)

OR

3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Fintepla

Diagnosis	Lennox-Gastaut Syndrome
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of seizures associated with Lennox-Gastaut syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - ONE of the following:

3.1 Trial and inadequate response, contraindication, or intolerance to TWO formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate) [2, A]

OR

3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Fintepla

Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by the reduction in seizure frequency from baseline</p>	

3 . Endnotes

- A. The International League Against Epilepsy (ILAE) refers to drug-resistant epilepsy as the failure of adequate trials of two tolerated, appropriately chosen, and used ASM schedules, whether as monotherapy or in combination, to achieve sustained seizure freedom [2]

4 . References

1. Fintepla prescribing information. Zogenix Inc. Emeryville, CA. March 2022.
2. Fattorusso, A., Matricardi et al. The Pharmacoresistant Epilepsy: An Overview on Existing and New Emerging Therapies. *Frontiers in Neurology*. June 2021. Available at <https://www.frontiersin.org/articles/10.3389/fneur.2021.674483/full>. Accessed May 6, 2022.
3. LGS Foundation. Lennox-Gastaut Syndrome. Available at <https://www.lgsfoundation.org/>. Accessed May 8, 2022.
4. UptoDate. Lennox-Gastaut Syndrome. Available at https://www.uptodate.com/contents/epilepsy-syndromes-in-children?search=lennox%20gastaut%20syndrome&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H9. Accessed May 8, 2022.

Flurazepam

Prior Authorization Guideline

Guideline Name	Flurazepam
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Flurazepam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of insomnia</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to two of the following benzodiazepines: [A]</p> <ul style="list-style-type: none">• Estazolam• Halcion (triazolam)	

- Restoril (temazepam)

2 . Endnotes

- A. Flurazepam, estazolam, triazolam, and temazepam are only recommended for patients < 65 years old. These drugs are included on the American Geriatrics Society 2015 Beers Criteria update. [2]

3 . References

1. Flurazepam prescribing information. West-ward Pharmaceutical Corp. Eatontown, NJ. December 2010.
2. The American Geriatrics Society 2015 Beers Criteria Update Expert Panel. American Geriatrics Society 2015 Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc.2015 Nov;63(11):2227-46. doi: 10.1111/jgs.13702

Prior Authorization Guideline

Guideline Name	Fotivda (tivozanib) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Fotivda
Renal cell carcinoma (RCC) Indicated for the treatment of adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies.

2 . Criteria

Product Name: Fotivda	
Diagnosis	Renal cell carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received two or more prior systemic therapies (e.g., chemotherapy)

AND

4 - Prescribed by or in consultation with one of the following:

- Oncologist
- Urologist

Product Name: Fotivda

Diagnosis	Renal cell carcinoma (RCC)
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received two or more prior systemic therapies (e.g., chemotherapy)

AND

4 - Prescribed by or in consultation with one of the following:

- Oncologist
- Urologist

Product Name: Fotivda	
Diagnosis	Renal cell carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Fotivda Prescribing Information. AVEO Pharmaceuticals, Inc. Boston, MA. March 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.4.2023. Available by subscription at:https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed April 28, 2023.

Prior Authorization Guideline

Guideline Name	Furoscix (furosemide injection) - PA, NF
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Furoscix (furosemide injection)
Congestion Indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. Limitations of use: FUROSCIX is not indicated for emergency situations or in patients with acute pulmonary edema.

2 . Criteria

Product Name: Furoscix	
Approval Length	3 Month(s) [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic heart failure	

AND

2 - Patient has New York Heart Association (NYHA) Class II or III

AND

3 - Patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide) [C]

AND

4 - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia) [B]

Product Name: Furoscix	
Approval Length	3 Month(s) [A]
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of chronic heart failure	
AND	
2 - Patient has New York Heart Association (NYHA) Class II or III	
AND	
3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient is currently on maintenance oral diuretic therapy (e.g., bumetanide, furosemide, torsemide) [C]	

AND

4 - Provider attests that patient will be closely monitored for fluid, electrolyte, and metabolic abnormalities throughout therapy (e.g., hypokalemia, hypovolemia, hyponatremia) [B]

3 . Endnotes

- A. Furoscix is not for chronic use and should be replaced with oral diuretics as soon as practical. [1]
- B. Furosemide may cause fluid, electrolyte, and metabolic abnormalities such as hypovolemia, hypokalemia, azotemia, hyponatremia, hypochloremic alkalosis, hypomagnesemia, hypocalcemia, hyperglycemia, or hyperuricemia, particularly in patients receiving higher doses, patients with inadequate oral electrolyte intake, and in elderly patients. Serum electrolytes, CO₂, BUN, creatinine, glucose, and uric acid should be monitored frequently during furosemide therapy. [1]
- C. Maintenance oral diuretic therapy includes those receiving 40-160 mg of oral furosemide equivalents daily (20-80 mg Torsemide or 1-4 mg Bumetanide). [3]

4 . References

- 1. Furoscix Prescribing Information. scPharmaceuticals, Inc. Burlington, MA. October 2022.
- 2. scPharmaceuticals, Inc. A Multicenter, Randomized, Open Label, Controlled Study Evaluating the Effectiveness and Safety of Furoscix On-Body Infusor vs Continued Medical Therapy for Worsening Heart Failure. clinicaltrials.gov. Published May 3, 2022.
- 3. scPharmaceuticals, Inc. Economic Impact of Reducing Hospital Admissions for Patients Presenting to the Emergency Department With Worsening Heart Failure: An Adaptive Clinical Trial of Furoscix Infusor. clinicaltrials.gov. Published July 9, 2021.

Galafold (migalastat)

Prior Authorization Guideline

Guideline Name	Galafold (migalastat)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Galafold (migalastat)
Fabry Disease Indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. This indication is approved based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Galafold	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Fabry Disease

AND

2 - One of the following: [3, 4]

- Detection of pathogenic mutations in the GLA gene by molecular genetic testing
- Deficiency in α -galactosidase A (α -Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS)
- Significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata)

AND

3 - Patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data [A]

AND

4 - Will not be used in combination with other drugs used for Fabry disease [B]

Product Name: Galafold

Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by one of the following: [3, 4]

- Reduction in plasma or urinary sediment lyso-GL-3, GL-3 compared to baseline
- Reduction in number of GL-3 inclusions per kidney interstitial capillary (KIC) in renal biopsy samples compared to baseline
- Improvement and/or stabilization in symptoms (e.g., renal function, neuropathic pain)

AND

2 - Will not be used in combination with other drugs used for Fabry disease [B]

3 . Endnotes

- A. In an in vitro assay (HEK-293 assay), Human Embryonic Kidney (HEK-293) cell lines were transfected with specific GLA variants (mutations) which produced mutant alpha-Gal A proteins. A GLA variant was categorized as amenable if the resultant mutant alpha-Gal A activity (measured in the cell lysates) met two criteria: 1) it showed a relative increase of at least 20% compared to the pre-treatment alpha-Gal A activity, and 2) it showed an absolute increase of at least 3% of the wild-type (normal) alpha-Gal A activity. Whether a certain amenable GLA variant in a patient with Fabry disease is disease-causing or not should be determined by the prescribing physician (in consultation with a clinical genetics professional, if needed) prior to treatment initiation. [1]
- B. The safety and effectiveness of concomitant use of Galafold and Fabrazyme (agalsidase beta) has not been established. [2]

4 . References

- 1. Galafold prescribing information. Amicus Therapeutics U.S., Inc. Cranbury, NJ. February 2021.
- 2. Per clinical consultation with geneticist. October 11, 2018.
- 3. Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. *Mol Genet Metab.* 2018;123(4):416-427. doi:10.1016/j.ymgme.2018.02.014.
- 4. Michaud M, Mauhin W, Belmatoug N, et al. When and How to Diagnose Fabry Disease in Clinical Practice. *Am J Med Sci.* 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

Prior Authorization Guideline

Guideline Name	Gamifant (emapalumab-lzsg)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Gamifant (emapalumab-lzsg)
Primary Hemophagocytic Lymphohistiocytosis (HLH) Indicated for the treatment of adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

2 . Criteria

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)	

AND

2 - One of the following:

2.1 Disease is one of the following:

- Refractory
- Recurrent
- Progressive

OR

2.2 Trial and failure, contraindication, or intolerance to conventional HLH therapy (e.g., etoposide, dexamethasone, cyclosporine A, intrathecal methotrexate)

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

AND

4 - Patient has not received hematopoietic stem cell transplantation (HSCT)

Product Name: Gamifant	
Approval Length	6 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., improvement in hemoglobin/lymphocyte/platelet counts, afebrile, normalization of inflammatory factors/markers)	

AND

2 - Patient has not received HSCT

3 . Endnotes

- A. Per clinical consultation, it is appropriate to limit authorization duration to no more than 6 months at a time, given that the ultimate goal in therapy is to receive HSCT and treatment with Gamifant should be viewed as bridge therapy to HSCT. Pivotal trial data duration was also less than 3 months. [2]

4 . References

1. Gamifant Prescribing Information. Sobi Inc. Waltham, MA. June 2020.
2. Per clinical consult with a pediatric hematologist/oncologist, January 18, 2019.

Gattex (teduglutide)

Prior Authorization Guideline

Guideline Name	Gattex (teduglutide)
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Guideline Note:

Effective Date:	6/15/2022
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1 . Indications

Drug Name: Gattex (teduglutide)
Short Bowel Syndrome (SBS) Indicated for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS) who are dependent on parenteral support.

2 . Criteria

Product Name: Gattex	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of short bowel syndrome	

AND

2 - Patient is 1 year of age and older

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months [A]

AND

4 - Prescribed by or in consultation with a gastroenterologist [C]

Product Name: Gattex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has had a reduction in weekly parenteral nutrition/intravenous (PN/IV) support from baseline while on Gattex therapy [B]	
AND	
2 - Prescribed by or in consultation with a gastroenterologist [C]	

3 . Endnotes

- A. Twelve consecutive months on parenteral nutrition is an inclusion criterion in clinical trials. [1]
- B. In clinical trial data, treatment with Gattex has been shown to reduce the volume and number of days that patients with short bowel syndrome require parenteral nutrition/intravenous (PN/IV) support, with some patients remaining on Gattex therapy even if PN/IV support was no longer required. [1, 6-8]
- C. Patients with short bowel syndrome (SBS) have undergone one or more surgical bowel resections due to underlying disease, congenital defects, or other trauma. These resections lead to inadequate digestion and absorption, requiring patients to become dependent on parenteral nutrition and/or intravenous (PN/IV) support. The management of PN/IV is complex and must be individualized to each patient as the degree of malabsorption can vary among patients with SBS. Long-term use of PN/IV can often lead to other complications, such as bacterial infections, blood clots, gallbladder disease, and liver and kidney problems. For SBS patients on chronic PN/IV, the goal of treatment is to reduce the need for PN/IV in order to improve the patients' quality of life and reduce the risk of any life-threatening complications. Careful monitoring of patients treated with Gattex is recommended in order to assess continued safety and manage any adverse effects or complications. [1-7]

4 . References

1. Gattex Prescribing Information. Shire-NPS Pharmaceuticals, Inc. Lexington, MA. June 2019.
2. Van Gossum A, Cabre E, Hébuterne X, et al. ESPEN Guidelines on Parenteral Nutrition: gastroenterology. *Clin Nutr.* 2009;28(4):415-27.
3. Nightingale J, Woodward JM on behalf of the Small Bowel and Nutrition Committee of the British Society of Gastroenterology. Guidelines for management of patients with a short bowel. *Gut.* 2006;55(Suppl 4):iv1-12.
4. National Institute of Diabetes and Digestive and Kidney Diseases. Short Bowel Syndrome. <https://www.niddk.nih.gov/health-information/digestive-diseases/short-bowel-syndrome>. Accessed December 7, 2020.
5. Buchman AL, Scolapio J, Fryer J. AGA technical review on short bowel syndrome and intestinal transplantation. *Gastroenterology.* 2003;124(4):1111-34.
6. Jeppesen PB, Pertkiewicz M, Messing B, et al. Teduglutide reduces need for parenteral support among patients with short bowel syndrome with intestinal failure. *Gastroenterology.* 2012;143(6):1473-1481.
7. Seidner DL, Schwartz LK, Winkler MF, Jeejeebhoy K, Boullata JI, Tappenden KA. Increased intestinal absorption in the era of teduglutide and its impact on management strategies in patients with short bowel syndrome-associated intestinal failure. *J Parenter Enteral Nutr.* 2013;37(2):201-11.
8. Naberhuis JK, Tappenden KA. Teduglutide for safe reduction of parenteral nutrient and/or fluid requirements in adults: a systematic review. *J Parenter Enteral Nutr.* 2016;40(8):1096-1105.

Prior Authorization Guideline

Guideline Name	Gaucher Disease Agents
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Cerezyme (imiglucerase for injection)
Type 1 Gaucher Disease Indicated for treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: - anemia - thrombocytopenia - bone disease - hepatomegaly or splenomegaly
Drug Name: Eleyso (taliglucerase alfa) for injection
Type 1 Gaucher Disease Indicated for the treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease.
Drug Name: VPRIV (velaglucerase alfa for injection)
Type 1 Gaucher Disease Indicated for long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease.
Drug Name: Cerdelga (eliglustat)
Type 1 Gaucher Disease Indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test. Limitations of Use: Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect. A specific

dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

Drug Name: Zavesca (miglustat)

Type 1 Gaucher Disease Indicated as monotherapy for the treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access).

2 . Criteria

Product Name: Cerezyme, Elelyso, or VPRIV

Approval Length | 12 month(s)

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

2 - Patient has evidence of symptomatic disease (e.g., moderate to severe anemia [A], thrombocytopenia [B], bone disease [C], hepatomegaly [D], or splenomegaly [D])

AND

3 - One of the following:

3.1 Patient is 4 years of age or older (applies to Elelyso and VPRIV only)

OR

3.2 Patient is 2 years of age or older (applies to Cerezyme only)

Product Name: Cerdelga	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Type 1 Gaucher disease</p> <p style="text-align: center;">AND</p> <p>2 - Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older</p>	

Product Name: Generic miglustat or Brand Zavesca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of mild to moderate Type 1 Gaucher disease [E]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older</p>	

3 . Endnotes

- A. Goals of treatment with anemia are to increase hemoglobin to greater than or equal to 12.0 g/dL for males (greater than 12 years of age), and to greater than or equal to 11.0 g/dL for both children (less than or equal to 12 years of age) and females (greater than 12 years of age). [6, 8]
- B. Moderate thrombocytopenia is defined as a platelet count of 60,000 to 120,000/microliter. A platelet count of 120,000/microliter to meet the criterion of thrombocytopenia is based on the upper end of the range that defines moderate thrombocytopenia. [6]
- C. In bone disease, the goal is to lessen or eliminate bone pain and prevent bone crises. Bone disease can be diagnosed using MRI, bone scan, and X-ray. [6-8]
- D. Hepatomegaly is defined as a liver mass of greater than 1.25 times normal value. Splenomegaly is defined as a splenic mass greater than the normal, and moderate splenomegaly is considered a spleen volume of greater than 5 and less than or equal to 15 times normal. [6]
- E. Zavesca may be prescribed only by physicians knowledgeable in the management of Gaucher disease (GD). In order to prescribe Zavesca, physicians must read the letter to doctors from Actelion, then sign and fax the one-page physician statement affirming that they are qualified to manage patients with GD and that they have read the Zavesca review booklet containing the full prescribing information. Zavesca is dispensed exclusively by Accredo specialty pharmacy. [10]

4 . References

1. Cerezyme Prescribing Information. Genzyme Corporation. Cambridge, MA. December 2021.
2. Eleyso Prescribing Information. Pfizer, Inc. New York, NY. July 2021.
3. VPRIV Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. September 2021.
4. Cerdelga Prescribing Information. Genzyme Ireland, Ltd. Waterford, Ireland. July 2021.
5. Zavesca Prescribing Information. Actelion Pharmaceuticals US, Inc. South San Francisco, CA. January 2021.
6. Pastores GM, Weinreb NJ, Aerts H, et al. Therapeutic goals in the treatment of Gaucher disease. *Semin Hematol.* 2004;41(4 Suppl 5):4-14.
7. Weinreb NJ, Aggio MC, Andersson HC, et al. Gaucher disease type 1: revised recommendations on evaluations and monitoring for adult patients. *Semin Hematol.* 2004;41(suppl 5):15-22.
8. Weinreb N, Taylor J, Cox T, et al. A benchmark analysis of the achievement of therapeutic goals for type 1 Gaucher disease patients treated with imiglucerase. *Am J Hematol.* 2008;83:890-895.
9. Hollak CE, vom Dahl S, Aerts JM, et al. Force majeure: therapeutic measures in response to restricted supply of imiglucerase (Cerezyme) for patients with Gaucher disease. *Blood Cells Mol Dis.* 2010;44(1):41-7.
10. Actelion Pharmaceuticals US, Inc. Zavesca (miglustat). Available at: <https://www.zavesca.com/hcp-home.html>. Accessed on December 29, 2021.
11. Per clinical consult with geneticist, November 11, 2010.

Gavreto (pralsetinib)

Prior Authorization Guideline

Guideline Name	Gavreto (pralsetinib)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Gavreto (pralsetinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.
RET Fusion-Positive Thyroid Cancer Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Gavreto	
Diagnosis	Lung Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">AND</p> <p>2 - Patient's disease has presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s) as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

Product Name: Gavreto	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of thyroid cancer</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Advanced • Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s)</p>	

AND

4 - Patient is 12 years of age or older

AND

5 - Disease requires treatment with systemic therapy

AND

6 - ONE of the following :

- Patient is radioactive iodine-refractory
- Radioactive iodine therapy is not appropriate

Product Name: Gavreto	
Diagnosis	Lung Cancer, Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Endocrinologist added in prescriber requirement to align with Retevmo. During Retevmo consult provider stated adding endocrinologist as an additional option.

4 . References

1. Gavreto Prescribing Information. Blueprint Medicines Corporation. Cambridge, MA. February 2022.

Prior Authorization Guideline

Guideline Name	Gilotrif (afatinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Gilotrif (afatinib)
<p>EGFR Mutation-Positive, Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of Gilotrif have not been established in patients whose tumors have resistant EGFR mutations.</p> <p>Previously Treated, Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) progressing after platinum-based chemotherapy.</p>

2 . Criteria

Product Name: Gilotrif	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic (stage IIIB or IV) non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an U.S. Food and Drug Administration (FDA) -approved test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

2.1.2 Gilotrif will be used as first-line treatment

OR

2.2 Both of the following:

2.2.1 Diagnosis of squamous NSCLC

AND

2.2.2 Disease progressed after platinum-based chemotherapy

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Gilotrif	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Gilotrif Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2019.

Prior Authorization Guideline

Guideline Name	Gleevec (imatinib mesylate) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Gleevec (imatinib mesylate)
<p>Chronic myelogenous/myeloid leukemia (CML) Indicated for the treatment of newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase. Gleevec is also indicated for the treatment of patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy.</p> <p>Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL) Indicated for the treatment of adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Gleevec is also indicated for the treatment of pediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy.</p> <p>Myelodysplastic/myeloproliferative diseases (MDS/MPD) Indicated for the treatment of adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.</p> <p>Aggressive systemic mastocytosis (ASM) Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown.</p> <p>Hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) Indicated for the treatment of adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFRa fusion kinase (mutational</p>

analysis or fluorescence in situ hybridization [FISH] demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1-PDGFRa fusion kinase negative or unknown.

Dermatofibrosarcoma protuberans (DFSP) Indicated for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP).

Gastrointestinal stromal tumors (GIST) Indicated for the treatment of patients with Kit (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). Gleevec is also indicated for the adjuvant treatment of adult patients following complete gross resection of Kit (CD117) positive GIST.

2 . Criteria

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <p>3.1 Trial and failure or intolerance to generic imatinib</p> <p style="text-align: center;">AND</p>	

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)</p>	

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

AND

3 - Both of the following:

3.1 Trial and failure or intolerance to generic imatinib

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)	
AND	
2 - Prescribed by or in consultation with a hematologist/oncologist	

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <p> 3.1 Trial and failure or intolerance to generic imatinib</p> <p style="text-align: center;">AND</p> <p> 3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of aggressive systemic mastocytosis (ASM)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • hematologist/oncologist • allergist/immunologist <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <p>3.1 Trial and failure or intolerance to generic imatinib</p> <p style="text-align: center;">AND</p>	

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of aggressive systemic mastocytosis (ASM)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • hematologist/oncologist • allergist/immunologist 	

Product Name: Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p>	

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

AND

3 - Both of the following:

3.1 Trial and failure or intolerance to generic imatinib

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Prescribed by or in consultation with one of the following:

- hematologist/oncologist
- allergist/immunologist

Product Name: Brand Gleevec

Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- dermatologist

AND

3 - Both of the following:

3.1 Trial and failure or intolerance to generic imatinib

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Dermatofibrosarcoma Protuberans (DFSP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
 Approval Criteria 1 - Diagnosis of unresectable, recurrent, or metastatic dermatofibrosarcoma protuberans (DFSP) <p style="text-align: center;">AND</p> 2 - Prescribed by or in consultation with one of the following: <ul style="list-style-type: none">• oncologist• dermatologist	

Product Name: Brand Gleevec	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- gastroenterologist

AND

3 - Both of the following:

3.1 Trial and failure or intolerance to generic imatinib

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic imatinib	
Diagnosis	Gastrointestinal Stromal Tumors (GIST)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumors (GIST)

AND

2 - Prescribed by or in consultation with one of the following:

- oncologist
- gastroenterologist

Product Name: Brand Gleevec, Generic imatinib

Diagnosis	All diagnoses listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Both of the following (applies to BRAND Gleevec only):

2.1 Trial and failure or intolerance to generic imatinib

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug

- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . References

1. Gleevec Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2021.

Prior Authorization Guideline

Guideline Name	GLP-1 Agonists
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Byetta (exenatide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Byetta is not indicated for use in patients with type 1 diabetes, 2) Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. 3) Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Bydureon BCise (exenatide extended-release)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: 1) Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans, 2) Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus, 3) Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide, 4) Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
Drug Name: Mounjaro (tirzepatide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Mounjaro has not been studied in patients with a history of pancreatitis. It is not indicated for use in patients with type 1 diabetes mellitus.

Drug Name: Ozempic (semaglutide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: 1) Ozempic has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy in patients with a history of pancreatitis, 2) Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Drug Name: Trulicity (dulaglutide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Limitations of Use: 1) Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis, 2) should not be used in patients with type 1 diabetes mellitus, 3) has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Drug Name: Victoza (liraglutide injection)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: 1) Victoza should not be used in patients with type 1 diabetes mellitus, 2) contains liraglutide and should not be coadministered with other liraglutide-containing products.

Drug Name: Rybelsus (semaglutide)

Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: (1) RYBELSUS is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. (2) RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. (3) RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus.

2 . Criteria

Product Name: Byetta, Bydureon BCise, Mounjaro, Rybelsus	
Diagnosis	Type 2 Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>2 - Drug is not solely being used for weight loss</p> <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes, lab values) confirming one of the following:</p> <p style="padding-left: 20px;">3.1 Currently on metformin for a minimum of 30 days and at a dose of 1500 mg/day or more</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">3.2 Trial and failure of a 30-day supply of metformin or metformin combination product and unable to reach a minimum dose of 1,500 mg/day due to intolerance despite appropriate dose titration duration</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">3.3 Contraindication to metformin per FDA label or not a metformin candidate (e.g., hepatic involvement, moderate renal dysfunction, or unstable heart failure)</p>	

OR

3.4 Patient has severe uncontrolled diabetes (as defined as 1.5% above goal per ADA guidelines) at diagnosis, and thus unlikely to achieve control with a single drug

Product Name: Ozempic, Trulicity, Victoza	
Diagnosis	Type 2 Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, lab values) confirming a diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>2 - Drug is not solely being used for weight loss</p> <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g. chart notes, lab values) confirming one of the following:</p> <p style="padding-left: 20px;">3.1 Currently on metformin for a minimum of 30 days and at a dose of 1500 mg/day or more</p> <p style="text-align: center;">OR</p> <p>3.2 Trial and failure of a 30-day supply of metformin or metformin combination product and unable to reach a minimum dose of 1,500 mg/day due to intolerance despite appropriate dose titration duration</p>	

OR

3.3 Contraindication to metformin per FDA label or not a metformin candidate (e.g., hepatic involvement, moderate renal dysfunction, or unstable heart failure)

OR

3.4 Patient requires GLP-1 agonist therapy due to ONE of the following:

3.4.1 Current atherosclerotic cardiovascular disease (ASCVD)

OR

3.4.2 Chronic Kidney Disease (CKD) stage III or higher

OR

3.4.3 CKD with albuminuria

OR

3.4.4 Both of the following:

3.4.4.1 Patient is 55 years or older

AND

3.4.4.2 Patient at high risk ASCVD has two or more risk factors:

- Duration of diabetes mellitus greater than 10 years
- Obesity
- Hypertension
- Smoking
- Family history of premature coronary artery disease
- Dyslipidemia

- Presence of albuminuria

OR

3.5 Patient has severe uncontrolled diabetes (as defined as 1.5% above goal per ADA guidelines) at diagnosis, and thus unlikely to achieve control with a single drug

Product Name: Byetta, Bydureon BCise, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza	
Diagnosis	Type 2 Diabetes Mellitus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, lab values) documenting a positive clinical response to therapy as evidenced by a reduction in HbA1C from baseline</p> <p style="text-align: center;">AND</p> <p>2 - Drug is not solely being used for weight loss</p>	

Product Name: Byetta, Bydureon BCise, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza	
Diagnosis	All other indications*
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI)</p>	

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section)

AND

2 - Submission of medical records (e.g., chart notes, lab values) documenting diagnosis

AND

3 - Drug is not solely being used for weight loss

Notes

*Do not use the off-label admin guideline for any indications

Product Name: Byetta, Bydureon BCise, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza

Diagnosis All other indications*

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI)

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section)

AND

2 - Drug is not solely being used for weight loss

AND

3 - Submission of medical records (e.g., chart notes, lab values) documenting a positive clinical response on appropriate monitoring parameter for diagnosis

Notes

*Do not use the off-label admin guideline for any indications

3 . References

1. Byetta Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. November 2021.
2. Victoza Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. December 2021.
3. Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN. December 2021.
4. Bydureon BCise Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. July 2021.
5. Ozempic Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2022.
6. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. September 2021.
7. American Diabetes Association. Standards of care in diabetes. Diabetes Care. 2024-01; 47 (suppl 1): S1-S321.
8. Mounjaro Prescribing Information. Eli Lilly and Company. Indianapolis, IN. May 2022.

Glumetza (metformin ER tablets)

Prior Authorization Guideline

Guideline Name	Glumetza (metformin ER tablets)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - One of the following: 1.1 Both of the following: 1.1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) [A]	

AND

1.1.2 Documented history of an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by Hemoglobin A1c level above patient's goal

OR

1.2 Documented history of intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of greater than or equal to 12 week trial of metformin immediate-release

AND

2.1.2 Documented history of an inadequate response to metformin immediate-release as evidenced by Hemoglobin A1c level above patient's goal

OR

2.2 Documented history of intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline

2 . Endnotes

- A. Prior authorization promotes use of cost-effective metformin options prior to approval of Glumetza (metformin extended release). Glucophage XR (metformin extended release) is also a 24 hour tablet preparation and is available generically [2].

3 . References

1. Glumetza prescribing information. Salix Pharmaceuticals. Bridgewater, NJ. April 2017.
2. Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: <http://online.lexi.com/>. Accessed August 20th, 2018

Prior Authorization Guideline

Guideline Name	Glycopyrrolate Oral Solution
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Glycopyrrolate oral solution
Chronic Severe Drooling (Sialorrhea) Indicated to reduce chronic severe drooling in patients aged 3 to 16 years with neurologic conditions associated with problem drooling (e.g., cerebral palsy).

2 . Criteria

Product Name: Generic glycopyrrolate oral solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic severe drooling (sialorrhea)	

AND

2 - Diagnosis of a neurologic condition (e.g., cerebral palsy) associated with chronic severe drooling (sialorrhea)

AND

3 - Patient is between 3 and 16 years of age

AND

4 - One of the following:

4.1 Trial and failure, or intolerance to generic glycopyrrolate tablets [A]

OR

4.2 Patient requires liquid formulation due to dosing or inability to take tablet formulation

Product Name: Generic glycopyrrolate oral solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy (e.g., reduction in drooling severity compared to baseline)	

3 . Endnotes

- A. Prior to the approval of glycopyrrolate oral solution, glycopyrrolate tablets were frequently and extensively used off-label in children to treat chronic drooling due to neurological conditions. [2, 3]

4 . References

1. Glycopyrrolate Oral Solution Prescribing Information. PAR Pharmaceutical. Chestnut Ridge, NY. February 2021.
2. Evatt ML. Oral glycopyrrolate for the treatment of chronic severe drooling caused by neurological disorders in children. *Neuropsychiatr Dis Treat*. 2011;7:543–7.
3. Cuvposa/Glycopyrrolate Center for Drug Evaluation and Research Summary Review. Food and Drug Administration Web site. <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process>. Accessed February 21, 2022.

Prior Authorization Guideline

Guideline Name	Glycopyrrolate Tablets - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Dartisla ODT (glycopyrrolate)
Peptic Ulcer, Adjunct Indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Limitations of Use: DARTISLA ODT is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.
Drug Name: Robinul, Robinul Forte (glycopyrrolate)
Peptic Ulcer, Adjunct Indicated for use as adjunctive therapy in the treatment of peptic ulcer.

2 . Criteria

Product Name: Dartisla ODT, Robinul, Robinul Forte	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of peptic ulcer as confirmed by endoscopy

AND

2 - One of the following: [2]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic glycopyrrolate tablets

OR

3.2 Patient is unable to swallow tablets (Applies to Dartisla ODT only)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Dartisla ODT, Robinul, Robinul Forte

Approval Length 3 Months [A]

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient's peptic ulcer has not healed as confirmed by endoscopy

OR

1.2 Patient has a new peptic ulcer as confirmed by endoscopy

AND

2 - One of the following: [2-3]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Patient experienced a reduction in peptic ulcer symptoms while on therapy

AND

4 - Other correctable factors (e.g., medication noncompliance, NSAID use, H. pylori infection, etc.) have been addressed

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Dartisla ODT

Approval Length	3 Months [A]
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Therapy Stage	Initial Authorization
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of peptic ulcer as confirmed by endoscopy

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [2]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

3.1 Trial and failure, or intolerance to generic glycopyrrolate tablets

OR

3.2 Patient is unable to swallow tablets

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Dartisla ODT

Approval Length	3 Months [A]
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming one of the following:

1.1 Patient's peptic ulcer has not healed as confirmed by endoscopy

OR

1.2 Patient has a new peptic ulcer as confirmed by endoscopy

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [2-3]

2.1 Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole)

OR

2.2 Both of the following:

2.2.1 Patient has a contraindication or intolerance to PPIs

AND

2.2.2 Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine)

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has experienced a reduction in peptic ulcer symptoms while on therapy

AND

4 - Submission of medical records (e.g., chart notes) confirming that other correctable factors (e.g., medication noncompliance, NSAID use, H. pylori infection, etc.) have been addressed

AND

5 - Prescribed by or in consultation with a gastroenterologist

3 . Endnotes

- A. Leading organizations and guidelines for peptic ulcer disease do not recommend glycopyrrolate as an option for the management of peptic ulcer. Due to the limited data available, Dartisla ODT treatment duration is based on current treatment guidance with antisecretory therapy which recommends initial treatment with a PPI for a maximum of 12 weeks, and an additional maximum 12 weeks for refractory ulcers, after which surgery should be considered. [2-3]

4 . References

1. Dartisla ODT Prescribing Information. Edenbridge Pharmaceuticals, LLC. Parsippany, NJ. December 2021.
2. Vakil NB. Peptic ulcer disease: Treatment and secondary prevention. UpToDate. Available by subscription at: <http://www.uptodate.com/>. Accessed February 9, 2022.
3. Vakil NB. Approach to refractory peptic ulcer disease. UpToDate. Available by subscription at: <http://www.uptodate.com/>. Accessed February 9, 2022.
4. Robinul/Robinul Forte Prescribing Information. Casper Pharma, LLC. East Brunswick, NJ. June 2021.

Prior Authorization Guideline

Guideline Name	Gonadotropin-Releasing Hormone Agonists
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Lupron Depot (leuprolide acetate) 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, Lupron Depot 6-Month 45 mg

Prostate Cancer Indicated for treatment of advanced prostatic cancer.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Lupron Depot 3.75 mg

Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with LUPRON DEPOT 3.75 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom

three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Lupron Depot 3-Month 11.25 mg

Endometriosis Indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions. In combination with a norethindrone acetate, it is also indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms. Limitations of Use: The total duration of therapy with LUPRON DEPOT 11.25 mg plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density.

Uterine Leiomyomata (Fibroids) Indicated for concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Limitations of Use: Not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would.

Drug Name: Leuprolide Acetate

Prostate Cancer Indicated for the palliative treatment of advanced prostatic cancer.

Off Label Uses: Infertility Used for controlled ovarian hyperstimulation to enhance the in vitro fertilization-embryo transfer (IVF-ET) procedure. [5]

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-

acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Leuprolide Acetate Depot

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Lupron Depot-PED (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated in the treatment of pediatric patients with central precocious puberty (CPP).

Off Label Uses: Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Eligard (leuprolide acetate)

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Supprelin LA (histrelin acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of children with CPP. Children with CPP (neurogenic or idiopathic) have an early onset of secondary sexual characteristics (earlier than 8 years of age in females and 9 years of age in males). They also

show a significantly advanced bone age that can result in diminished adult height attainment. Prior to initiation of treatment a clinical diagnosis of CPP should be confirmed by measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog, and assessment of bone age versus chronological age. Baseline evaluations should include height and weight measurements, diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor), and adrenal steroids to exclude congenital adrenal hyperplasia.

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Trelstar (triptorelin pamoate)

Prostate Cancer Indicated for the palliative treatment of advanced prostate cancer.

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

Drug Name: Triptodur (triptorelin)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Gender Dysphoria [16, 17] Suppression of pubertal development and gonadal function is accomplished most effectively by gonadotropin suppression with gonadotropin releasing hormone analogues and antagonists. Analogues suppress gonadotropins after a short period of stimulation, whereas antagonists immediately suppress pituitary secretion. Since no long-acting antagonists are available for use as pharmacotherapy, long-acting analogues are the currently preferred treatment option. [16] Early use of puberty-suppressing hormones may avert negative social and emotional consequences of gender dysphoria more effectively than their later use would. [17]

2 . Criteria

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of endometriosis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [8, 12]</p> <p>2.1 History of inadequate pain control response following a trial of at least 6 months, or history of intolerance or contraindication to one of the following:</p> <ul style="list-style-type: none"> • Danazol • Combination (estrogen/progestin) oral contraceptive • Progestins <p style="text-align: center;">OR</p> <p>2.2 Patient has had surgical ablation to prevent recurrence</p>	

Product Name: Lupron Depot (3.75 mg and 11.25 mg)	
Diagnosis	Endometriosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Recurrence of symptoms following a trial of at least 6 months with leuprolide acetate

AND

2 - Used in combination with one of the following:

- Norethindrone 5 mg daily
- Other "add-back" sex-hormones (e.g., estrogen, medroxyprogesterone)
- Other bone-sparing agents (e.g., bisphosphonates)

Product Name: Lupron Depot (3.75 mg and 11.25 mg)

Diagnosis	Uterine Leiomyomata (Fibroids) - For the reduction of the size of fibroids [off-label]
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Approval Length	4 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - For use prior to surgery to reduce the size of fibroids to facilitate a surgical procedure (e.g., myomectomy, hysterectomy) [5]

Product Name: Lupron Depot (3.75 mg and 11.25 mg)

Diagnosis	Uterine Leiomyomata (Fibroids) - Anemia [4, 6]
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Approval Length	3 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - For the treatment of anemia

AND

2 - Anemia is caused by uterine leiomyomata (fibroids)

AND

3 - Patient has tried and had an inadequate response to at least 1 month of monotherapy with iron

AND

4 - Used in combination with iron therapy

AND

5 - For use prior to surgery

Product Name: Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of central precocious puberty (idiopathic or neurogenic)	
AND	
2 - Early onset of secondary sexual characteristics in one of the following:	
<ul style="list-style-type: none">• Females less than 8 years of age• Males less than 9 years of age	

AND

3 - Advanced bone age of at least one year compared with chronological age

AND

4 - One of the following:

4.1 Both of the following:

- Patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing
- Peak luteinizing hormone (LH) level above pre-pubertal range

OR

4.2 Patient has a random LH level in the pubertal range

AND

5 - One of the following:

5.1 Patient had one of the following diagnostic evaluations to rule out tumors, when suspected:

- Diagnostic imaging of the brain (MRI or CT scan) (in patients with symptoms suggestive of a brain tumor or in those 6 years of age or younger)
- Pelvic/testicular/adrenal ultrasound (if steroid levels suggest suspicion)
- Adrenal steroids to rule out congenital adrenal hyperplasia (when pubarche precedes thelarche or gonadarche)

OR

5.2 Patient has no suspected tumors

AND

6 - Prescribed by or in consultation with a pediatric endocrinologist

Product Name: Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age, improvement in final height prediction, LH levels have been suppressed to pre-pubertal levels</p> <p style="text-align: center;">AND</p> <p>2 - Patient is currently younger than the appropriate time point for the onset of puberty (e.g., females younger than 11 years of age, males younger than 12 years of age) [18]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a pediatric endocrinologist</p>	

Product Name: Generic leuprolide acetate*	
Diagnosis	Treatment of Infertility (off-label) [5]
Approval Length	2 Month [A] (or per plan benefit design)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of infertility</p> <p style="text-align: center;">AND</p>	

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes

*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity.

Product Name: Eligard, Leuprolide Acetate, generic leuprolide acetate, Trelstar

Diagnosis Prostate Cancer

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [4, 14]

AND

2 - Trial and failure, contraindication, or intolerance to any brand Lupron formulation

Product Name: Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg)

Diagnosis Prostate Cancer

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of advanced or metastatic prostate cancer [5, 14]

Product Name: Eligard, Leuprolide Acetate, generic leuprolide acetate, Lupron Depot (7.5 mg, 22.5 mg, 30 mg and 45 mg), Trelstar

Diagnosis Prostate Cancer

Approval Length 12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Lupron Depot, Lupron Depot-PED, Leuprolide Acetate, generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [18, 19]
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Using gonadotropin for suppression of puberty [16,17]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of gender dysphoria/gender incongruence</p>	

3 . Endnotes

- A. Sixty days would be a reasonable length of authorization for the treatment of infertility. [13]

4 . References

1. Leuprolide acetate prescribing information. Sandoz Inc. Princeton, NJ. June 2020.
2. Lupron Depot (3.75 mg) prescribing information. AbbVie Inc. North Chicago, IL. July 2022.
3. Lupron Depot (3-Month 11.25 mg) prescribing information. AbbVie Inc. North Chicago, IL. March 2020.

4. Friedman AJ, Harrison-Atlas D, Barbieri RL, et al. A randomized, placebo-controlled, double-blind study evaluating the efficacy of leuprolide acetate depot in the treatment of uterine leiomyomata. *Fertil Steril* 1989;51:251-256.
5. DRUGDEX System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Updated periodically. Accessed August 31, 2022.
6. Lethaby A, Vollenhoven B, Sowter M. Pre-operative GnRH analogue therapy before hysterectomy or myomectomy for uterine fibroids. *Cochrane Database Syst Rev*. 2001;(2):CD000547.
7. Supprelin LA prescribing information. Endo Pharmaceutical Inc. Malvern, PA. April 2022.
8. Ferrero, S., Barra, F. & Leone Roberti Maggiore, U. Current and Emerging Therapeutics for the Management of Endometriosis. *Drugs* 78, 995–1012 (2018).
9. Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg) prescribing information. AbbVie Inc. North Chicago, IL. April 2022.
10. Eligard prescribing information. Tolmar Pharmaceuticals, Inc. Fort Collins, CO. April 2019.
11. Trelstar prescribing information. Verity Pharmaceuticals, Inc. Wayne, PA. October 2020.
12. Practice bulletin no. 114: management of endometriosis. *Obstet Gynecol*. 2010 Jul; 116 (1): 223-36.
13. Per clinical consult with reproductive endocrinologist, April 10, 2013.
14. National Comprehensive Cancer Network Drugs and Biologics Compendium (NCCN Compendium). Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 31, 2022.
15. Lupron Depot-PED prescribing information. AbbVie Inc. North Chicago, IL. April 2023.
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17. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *International Journal of Transgenderism*. 13:165-232, 2011.
18. Triptodur prescribing information. Arbor Pharmaceuticals, LLC. Atlanta, GA. December 2022.
19. Leuprolide Acetate Depot Prescribing Information. Cipla USA, Inc. Warren, NJ. March 2023.
20. Harrington, J, Palmert, M. Treatment of precocious puberty. UpToDate. 2022. https://www.uptodate.com/contents/treatment-of-precocious-puberty?search=central%20precocious%20puberty&source=search_result&selectedTitle=2~30&usage_type=default&display_rank=2. Accessed August 2, 2023.

Prior Authorization Guideline

Guideline Name	Gonadotropins - PA, NF
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Follistim AQ (follitropin beta)
Ovulation Induction Indicated for the induction of ovulation and pregnancy in anovulatory infertile women in whom the cause of infertility is functional and not due to primary ovarian failure.
Spermatogenesis Induction Indicated for the induction of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism (HH) in whom the cause of infertility is not due to primary testicular failure.
Controlled Ovarian Stimulation in association with Assisted Reproductive Technology Indicated for pregnancy in normal ovulatory women undergoing controlled ovarian stimulation as part of an in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) cycle.
Drug Name: Gonal-F (follitropin alfa)
Ovulation Induction Indicated for the induction of ovulation and pregnancy in oligo-anovulatory infertile women for whom the cause of infertility is functional and not due to primary ovarian failure.
Controlled Ovarian Stimulation in association with Assisted Reproductive Technology Indicated for the development of multiple follicles in ovulatory infertile women as part of an assisted reproductive technology (ART) cycle.
Spermatogenesis Induction Indicated for the induction of spermatogenesis in infertile men

with primary and secondary hypogonadotropic hypogonadism for whom the cause of infertility is not due to primary testicular failure.

Drug Name: Gonal-F RFF (follitropin alfa)

Controlled Ovarian Stimulation in association with Assisted Reproductive Technology [1-5] Indicated for the development of multiple follicles in ovulatory infertile women as part of an assisted reproductive technology (ART) cycle.

Ovulation Induction Indicated for the induction of ovulation and pregnancy in oligo-anovulatory infertile women for whom the cause of infertility is functional and not due to primary ovarian failure.

Off Label Uses: Spermatogenesis Induction [6, 7] Used for the treatment of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure. A menotropin, Pergonal, has a spermatogenesis induction indication where clinical studies showed after 3 months of treatment, sperm counts increased from 5 million spermatozoa per mL of ejaculate to 24 mL and successful pregnancy rates were observed. [10]

Drug Name: Menopur (menotropins)

Controlled Ovarian Stimulation in association with Assisted Reproductive Technology Indicated for the development of multiple follicles and pregnancy in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle.

Off Label Uses: Ovulation Induction [6, 7] Used for the treatment of ovulation induction in patients with polycystic ovary syndrome who failed on clomiphene. The ovulation rate compared to Gonal-f was non-inferior, at rates of 85.7% and 85.5% respectively. [8] In other studies, rates of ovulation of 95% and pregnancy rates of 58% to 72% are demonstrated. Because of its high cost, higher incidence of serious side effects, and difficult of administration menotropins are usually reserved to treat patients who have failed to respond to therapy with clomiphene. [9]

Spermatogenesis Induction [6, 7] Used for the treatment of spermatogenesis in men with primary and secondary hypogonadotropic hypogonadism in whom the cause of infertility is not due to primary testicular failure. A menotropin, Pergonal, has a spermatogenesis induction indication where clinical studies showed after 3 months of treatment, sperm counts increased from 5 million spermatozoa per mL of ejaculate to 24 mL and successful pregnancy rates were observed. [10]

2 . Criteria

Product Name: Follistim AQ

Diagnosis

Ovulation Induction

Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Provided it is not a benefit exclusion</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of anovulatory infertility</p> <p style="text-align: center;">AND</p> <p>3 - Infertility is not due to primary ovarian failure</p> <p style="text-align: center;">AND</p> <p>4 - For induction of ovulation</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a reproductive endocrinologist</p>	

Product Name: Gonal-f, Gonal-f RFF, Menopur (off-label)	
Diagnosis	Ovulation Induction
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Provided it is not a benefit exclusion</p>	

AND

2 - Diagnosis of anovulatory infertility

AND

3 - Infertility is not due to primary ovarian failure

AND

4 - For induction of ovulation

AND

5 - One of the following:

5.1 Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [A]

OR

5.2 Patient has a condition that requires use of drug that contains both luteinizing hormone (LH) and follicle-stimulating hormone (FSH) (applies to Menopur only)

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Gonal-f, Gonal-f RFF	
Diagnosis	Ovulation Induction
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Non Formulary

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of anovulatory infertility

AND

3 - Infertility is not due to primary ovarian failure

AND

4 - For induction of ovulation

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [A]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Follistim AQ	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of infertility

AND

3 - For the development of multiple follicles (controlled ovarian hyperstimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program

AND

4 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Gonal-f, Gonal-f RFF, Menopur

Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - Diagnosis of infertility

AND

3 - For the development of multiple follicles (controlled ovarian hyperstimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program

AND

4 - One of the following:

4.1 Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [B]

OR

4.2 Concomitant use with Follistim AQ is required (applies to Menopur only)

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Gonal-f, Gonal-f RFF	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 months [D] (or per plan benefit design)
Guideline Type	Non Formulary
Approval Criteria	
1 - Provided it is not a benefit exclusion	
AND	
2 - Diagnosis of infertility	
AND	
3 - For the development of multiple follicles (controlled ovarian hyperstimulation) in an ovulatory female patient participating in an Assisted Reproductive Technology (ART) program	

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [B]

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Follistim AQ

Diagnosis	Male Hypogonadotropic Hypogonadism
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Approval Length	2 months [D] (or per plan benefit design)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - One of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Infertility is not due to primary testicular failure

AND

5 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Gonal-f, Gonal-f RFF (off-label), Menopur (off-label)

Diagnosis	Male Hypogonadotropic Hypogonadism
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Approval Length	2 months [D] (or per plan benefit design)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - One of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Infertility is not due to primary testicular failure

AND

5 - Trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [C]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

Product Name: Gonal-f, Gonal-f RFF (off-label)

Diagnosis	Male Hypogonadotropic Hypogonadism
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Approval Length	2 months [D] (or per plan benefit design)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Provided it is not a benefit exclusion

AND

2 - One of the following:

- Diagnosis of male primary hypogonadotropic hypogonadism
- Diagnosis of male secondary hypogonadotropic hypogonadism

AND

3 - For induction of spermatogenesis

AND

4 - Infertility is not due to primary testicular failure

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, intolerance, or contraindication to Follistim AQ (follitropin beta) [C]

AND

6 - Prescribed by or in consultation with a reproductive endocrinologist

3 . Endnotes

- A. There is no consensus definition of poor responder to gonadotropins in the setting of ovulation induction. [11, 12, 14, 15, 16] One study looked at ovulation induction failure with gonadotropin specifically. [11] Poor response in this study was defined as maximum dose of 450 IU gonadotropin daily for 9 days and either: (i) < 4 oocytes obtained at oocyte retrieval, or (ii) cycle cancellation prior to oocyte retrieval because of poor follicular development (< 3 follicles of > 14 mm after 9-12 days of stimulation).
- B. There is no consensus definition of poor responder to gonadotropins in the setting of ovarian stimulation in association with ART. [11, 12, 14, 15, 16] The most cited definition of poor responders was: number of mature follicles < 2-5; number of mature oocytes retrieved < 3; single dominant follicle; mean daily gonadotropin dose > 300 IU; and total gonadotropin dose > 40 ampules. [11]
- C. There is no consensus definition of poor responder to gonadotropins in the setting of spermatogenesis induction in men with hypogonadotropic hypogonadism. Outcomes measured for response include time to achieve first sperm, time to conception, and sperm concentration, but poor response was not well-defined. [13, 17] A combined analysis looked at four clinical trials and used the common efficacy outcome of spermatozoa concentration of greater than or equal 1.5×10^6 /mL. [13]
- D. Sixty days would be a reasonable length of authorization for all of the indications. [21]

4 . References

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 21. Per clinical consult with reproductive endocrinologist, April 10, 2013.

Prior Authorization Guideline

Guideline Name	Growth Hormones - PA, NF
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, Saizen, and Zomacton
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients with growth failure due to inadequate secretion of endogenous growth hormone.
Drug Name: Skytrofa (lonapegsomatropin-tcgd)
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).
Drug Name: Ngenla (somatrogon-ghla)
Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients aged 3 years and older who have growth failure due to an inadequate secretion of endogenous growth hormone.
Drug Name: Genotropin and Omnitrope
Prader-Willi Syndrome (PWS) Indicated for the treatment of pediatric patients who have growth failure due to Prader-Willi Syndrome (PWS). The diagnosis of PWS should be confirmed by appropriate genetic testing.

Small for Gestational Age (SGA) Indicated for the treatment of growth failure in children born small for gestational age (SGA) who fail to manifest catch-up growth by age 2.

Drug Name: Norditropin Flexpro, Humatrope, and Zomacton

Small for Gestational Age (SGA) Indicated for the treatment of pediatric patients with short stature born small for gestational age (SGA) with no catch-up growth by 2 years to 4 years of age.

Drug Name: Genotropin, Humatrope, Norditropin Flexpro, Nutropin AQ NuSpin, Omnitrope, and Zomacton

Turner Syndrome Indicated for the treatment of pediatric patients with short stature associated with Turner syndrome.

Drug Name: Humatrope and Zomacton

SHOX Deficiency Indicated for the treatment of pediatric patients with short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency.

Drug Name: Nutropin AQ NuSpin

Growth Failure Secondary to Chronic Kidney Disease (CKD) Indicated for the treatment of growth failure associated with CKD up to the time of renal transplantation. Nutropin AQ therapy should be used in conjunction with optimal management of CKD.

Drug Name: Norditropin Flexpro

Noonan Syndrome Indicated for the treatment of pediatric patients with short stature associated with Noonan Syndrome.

Prader-Willi Syndrome Indicated for the treatment of pediatric patients with growth failure due to Prader-Willi syndrome (PWS).

Drug Name: Genotropin, Nutropin AQ NuSpin, and Omnitrope

[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of idiopathic short stature, also called non-growth hormone-deficient short stature, defined by height SDS less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, in pediatric patients whose epiphyses are not closed and for whom diagnostic evaluation excludes other causes associated with short stature that should be observed or treated by other means. ****Please Note:** The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Drug Name: Norditropin Flexpro and Humatrope

[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. ****Please Note:** The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Drug Name: Genotropin, Nutropin AQ NuSpin, Omnitrope, and Saizen

Adult Growth Hormone Deficiency Indicated for replacement of endogenous growth hormone in adults with growth hormone deficiency who meet either of the following two criteria: **Adult-Onset:** Patients who have growth hormone deficiency, either alone or associated with multiple hormone deficiencies (hypopituitarism), as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, or trauma; or **Childhood-Onset:** Patients who were growth hormone deficient during childhood as a result of congenital, genetic, acquired, or idiopathic causes. Patients who were treated with somatropin for growth hormone deficiency in childhood and whose epiphyses are closed should be reevaluated before continuation of somatropin therapy at the reduced dose level recommended for growth hormone deficient adults. Confirmation of the diagnosis of adult growth hormone deficiency in both groups involves an appropriate growth hormone provocative test with two exceptions: (1) patients with multiple other pituitary hormone deficiencies due to organic disease; and (2) patients with congenital/genetic growth hormone deficiency.

Drug Name: Norditropin Flexpro, Humatrope, and Zomacton

Adult Growth Hormone Deficiency Indicated for the replacement of endogenous GH in adults with GH deficiency.

Drug Name: Serostim

AIDS Wasting or Cachexia Indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary.

Drug Name: Zorbtive

Short Bowel Syndrome Indicated for the treatment of short bowel syndrome in adult patients receiving specialized nutritional support.

Drug Name: Zomacton

[Non-Approvable Use] Idiopathic Short Stature (ISS) [E] Indicated for the treatment of pediatric patients with Idiopathic Short Stature (ISS), height standard deviation score (SDS) less than or equal to -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range. ****Please Note:** The request for growth hormone (GH) injections to treat idiopathic short stature (ISS) is not authorized. There is no consensus in

current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy.

Drug Name: Sogroya (somapacitan-beco)

Pediatric Growth Hormone Deficiency Indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).

Adult Growth Hormone Deficiency Indicated for the replacement of endogenous GH in adults with growth hormone deficiency (GHD).

2 . Criteria

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 One of the following: [12]</p> <p>1.1.1 Both of the following: [24-26]</p> <ul style="list-style-type: none"> • Infant is less than 4 months of age • Infant has suspected GH deficiency based on clinical presentation (e.g., persistent neonatal hypoglycemia, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive, etc.) <p style="text-align: center;">OR</p> <p>1.1.2 History of neonatal hypoglycemia associated with pituitary disease</p>	

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes

Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. *Approve at NDC list "SOMATROPPA".

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*

Diagnosis

Pediatric Growth Hormone Deficiency (GHD)

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes

Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency. *Approve at NDC list "SOMATROPPA".

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 One of the following: [12]</p> <p>1.1.1 Both of the following: [24-26]</p> <ul style="list-style-type: none"> • Infant is less than 4 months of age • Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.) <p style="text-align: center;">OR</p> <p>1.1.2 History of neonatal hypoglycemia associated with pituitary disease</p> <p style="text-align: center;">OR</p> <p>1.1.3 Diagnosis of panhypopituitarism</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]</p> <p>1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]</p> <ul style="list-style-type: none"> • Height is greater than 2.0 standard deviations [SD] below midparental height 	

- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon

- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes	Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.
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	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.
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Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 One of the following: [12]</p> <p>1.1.1 Both of the following: [24-26]</p> <ul style="list-style-type: none"> • Infant is less than 4 months of age • Suspected GHD based on clinical presentation (e.g., persistent neonatal hypoglycemia that is not responsive to treatment, persistent or prolonged neonatal jaundice/elevated bilirubin, male infant with microgenitalia, midline anatomical defects, etc.) <p style="text-align: center;">OR</p> <p>1.1.2 History of neonatal hypoglycemia associated with pituitary disease</p> <p style="text-align: center;">OR</p> <p>1.1.3 Diagnosis of panhypopituitarism</p> <p style="text-align: center;">OR</p> <p>1.2 Submission of medical records (e.g., chart notes) documenting all of the following:</p> <p>1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]</p> <p>1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]</p> <ul style="list-style-type: none"> • Height is greater than 2.0 standard deviations [SD] below midparental height 	

- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 One of the following:

1.2.3.1 Both of the following: [10, 11, 12]

1.2.3.1.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon

- Insulin
- Levodopa

AND

1.2.3.1.2 Both GH response values are less than 10 mcg/L

OR

1.2.3.2 Both of the following: [11]

1.2.3.2.1 Patient is less than 1 year of age

AND

1.2.3.2.2 One of the following is below the age and gender adjusted normal range as provided by the physician's lab: [A, 13, 14]

- Insulin-like Growth Factor 1 (IGF-1/Somatomedin-C)
- Insulin Growth Factor Binding Protein-3 (IGFBP-3)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

Includes children who have undergone brain radiation. If patient is a Transition Phase Adolescent or Adult who had childhood onset GH deficiency, utilize criteria for Transition Phase Adolescent or Adult GH Deficiency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p> <ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 One of the following: [12]</p> <p>1.1.1 History of neonatal hypoglycemia associated with pituitary disease</p> <p style="text-align: center;">OR</p> <p>1.1.2 Diagnosis of panhypopituitarism</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]</p> <p>1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]</p> <ul style="list-style-type: none"> • Height is greater than 2.0 standard deviations [SD] below midparental height • Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender) <p style="text-align: center;">OR</p> <p>1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender</p> <p style="text-align: center;">OR</p>	

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Skytrofa

Diagnosis | Pediatric Growth Hormone Deficiency (GHD)

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria	
1 - One of the following:	
1.1 One of the following: [12]	
1.1.1 History of neonatal hypoglycemia associated with pituitary disease	
OR	

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) documenting diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 One of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 1 year of age or older

AND

3 - Patient weight is 11.5 kg or greater

AND

4 - Prescribed by or in consultation with an endocrinologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

<ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	
Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Skytrofa	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p>	

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 One of the following: [12]</p> <p>1.1.1 History of neonatal hypoglycemia associated with pituitary disease</p> <p style="text-align: center;">OR</p> <p>1.1.2 Diagnosis of panhypopituitarism</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]</p> <p>1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]</p> <ul style="list-style-type: none"> • Height is greater than 2.0 standard deviations [SD] below midparental height 	

- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin

- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 2.5 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.
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Product Name: Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Ngenla	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	

1.1 One of the following: [12]

1.1.1 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.2 Diagnosis of panhypopituitarism

OR

1.2 All of the following:

1.2.1 Diagnosis of pediatric GH deficiency as confirmed by one of the following: [10, 11, 12]

1.2.1.1 Height is documented by one of the following (utilizing age and gender growth charts related to height): [11]

- Height is greater than 2.0 standard deviations [SD] below midparental height
- Height is greater than 2.25 SD below population mean (below the 1.2 percentile for age and gender)

OR

1.2.1.2 Growth velocity is greater than 2 SD below mean for age and gender

OR

1.2.1.3 Delayed skeletal maturation of greater than 2 SD below mean for age and gender (e.g., delayed greater than 2 years compared with chronological age)

AND

1.2.2 Documentation of one of the following: [22]

1.2.2.1 Both of the following:

- Patient is male

- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

1.2.3 Both of the following: [10, 11, 12]

1.2.3.1 Patient has undergone two of the following provocative GH stimulation tests:

- Arginine
- Clonidine
- Glucagon
- Insulin
- Levodopa

AND

1.2.3.2 Both GH response values are less than 10 mcg/L

AND

2 - Patient is 3 years of age or older

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

<ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	
Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Ngenla	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22, 23]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to one of the following: [B]</p>	

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label], Omnitrope* [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Prader-Willi Syndrome [10, 11]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p>	
Notes	*Approve at NDC list "SOMATROPPIA".

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label], Omnitrope* [B, 11]	
Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)</p>	

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]

Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]

Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained

- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]

Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope [off-label], Saizen [off-label], Zomacton [off-label] [B, 11]

Diagnosis	Prader-Willi Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Evidence of positive response to therapy (e.g., increase in total lean body mass, decrease in fat mass)

OR

1.2 Submission of medical records (e.g., chart notes) documenting both of the following:

1.2.1 Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

1.2.2 Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label] [B, 11], Omnitrope*	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]	
1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below population mean):	
<ul style="list-style-type: none">• Birth weight	

<ul style="list-style-type: none"> • Birth length 	
AND	
<p>2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]</p>	
AND	
<p>3 - Prescribed by or in consultation with an endocrinologist</p>	
Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. *Approve at NDC list "SOMATROPPIA".

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label] [B, 11], Omnitrope*	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal 	

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton

Diagnosis

Growth Failure in Children Small for Gestational Age (SGA)

Approval Length

12 month(s)

Therapy Stage

Initial Authorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]

1.1 One of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):

- Birth weight
- Birth length

AND

2 - Height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

<ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	
Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to one of the following: [B]</p>	

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of SGA based on demonstration of catch up growth failure in the first 24 months of life using a 0-36 month growth chart as confirmed by the following criterion: [10]</p> <p>1.1 Submission of medical records (e.g., chart notes) documenting one of the following is below the 3rd percentile for gestational age (more than 2 SD below the population mean):</p> <ul style="list-style-type: none"> • Birth weight • Birth length <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting height remains less than or equal to 3rd percentile (more than 2 SD below population mean) [10]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p>	

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Growth Failure in Children Small for Gestational Age (SGA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p> <ul style="list-style-type: none"> • Norditropin (somatropin) 	

- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label] [B, 11], Omnitrope*

Diagnosis	Turner Syndrome or Noonan Syndrome
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. *Approve at NDC list "SOMATROPPIA".
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Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin* [off-label] [B,11], Omnitrope*	
Diagnosis	Turner Syndrome or Noonan Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained 	

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPE".

Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis

Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]

Approval Length

12 month(s)

Therapy Stage

Initial Authorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]

1.1 Both of the following:

1.1.1 Turner Syndrome (Gonadal Dysgenesis)

AND

1.1.2 Documentation of both of the following:

- Patient is female
- Bone age less than 14 years

OR

1.2 Both of the following:

1.2.1 Noonan Syndrome

AND

1.2.2 Documentation of one of the following:

1.2.2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Height is below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.
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Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of pediatric growth failure associated with one of the following: [10, 22]</p> <p>1.1 Both of the following:</p> <p>1.1.1 Turner Syndrome (Gonadal Dysgenesis)</p> <p style="text-align: center;">AND</p> <p>1.1.2 Submission of medical records (e.g., chart notes) documenting both of the following:</p> <ul style="list-style-type: none"> • Patient is female • Bone age less than 14 years <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 Noonan Syndrome</p> <p style="text-align: center;">AND</p> <p>1.2.2 Submission of medical records (e.g., chart notes) documenting one of the following:</p> <p>1.2.2.1 Both of the following:</p> <ul style="list-style-type: none"> • Patient is male • Bone age less than 16 years 	

OR

1.2.2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

2 - Submission of medical records (e.g., chart notes) documenting height below the 5th percentile on growth charts for age and gender [10]

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Turner Syndrome [off-label for Saizen] or Noonan Syndrome [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria	

1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claim or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.*Approve at NDC list "S OMATROPPE".
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Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*

Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPIA".
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Product Name: Genotropin [off-label], Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of one of the following: [22]</p> <p>2.1 Both of the following:</p> <ul style="list-style-type: none"> • Patient is male • Bone age less than 16 years 	

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label] [B, 11], Zomacton

Diagnosis Short-Stature Homeobox (SHOX) Gene Deficiency

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of pediatric growth failure with short stature homeobox (SHOX) gene deficiency as confirmed by genetic testing [2]	
AND	
2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]	

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin [off-label], Humatrope, Saizen [off-label] [B, 11], Zomacton	
Diagnosis	Short-Stature Homeobox (SHOX) Gene Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]	

- Previous height and date obtained
- Current height and date obtained

AND

2 - Submission of medical records (e.g., chart notes) documenting both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Norditropin Flexpro* [off-label] [B, 11], Nutropin AQ NuSpin*, Omnitrope* [off-label] [B, 11]

Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.*Approve at NDC list "S OMATROPPE".
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Product Name: Norditropin Flexpro* [off-label] [B, 11], Nutropin AQ NuSpin*, Omnitrope* [off-label][B, 11]	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis

Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]

Approval Length

12 month(s)

Therapy Stage

Initial Authorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Documentation of one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal.

Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height not attained
- Documentation of expected adult height goal

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of pediatric growth failure associated with chronic renal insufficiency [10]

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [22]

2.1 Both of the following:

- Patient is male
- Bone age less than 16 years

OR

2.2 Both of the following:

- Patient is female
- Bone age less than 14 years

AND

3 - Prescribed by or in consultation with one of the following:

- Endocrinologist
- Nephrologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Growth Failure associated with Chronic Renal Insufficiency [off-label] [B, 11]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [22]</p> <ul style="list-style-type: none"> • Previous height and date obtained • Current height and date obtained <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting both of the following:</p> <ul style="list-style-type: none"> • Expected adult height not attained • Documentation of expected adult height goal <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Endocrinologist • Nephrologist <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p> <ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) 	

- Omnitrope (somatropin)

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*

Diagnosis	Adult Growth Hormone Deficiency
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Clinical records supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 20-21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)

- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- Adrenocorticotrophic hormone (ACTH)
- Thyroid stimulating hormone (TSH)
- Follicle-stimulating hormone/luteinizing hormone (FSH/LH)

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease. *Approve at NDC list "SOMATROPPE".
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Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p>	
Notes	Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.*Approve at NDC list "SOMATROPPA".

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]</p> <p>1.1 Clinical records supporting a diagnosis of childhood-onset GHD</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 Adult-onset GHD</p> <p style="text-align: center;">AND</p>	

1.2.2 Clinical records documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Documented deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p>	

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21]	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]</p> <p>1.1 Submission of medical records (e.g., chart notes) supporting a diagnosis of childhood-onset GHD</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 Adult-onset GHD</p> <p style="text-align: center;">AND</p> <p>1.2.2 Submission of medical records (e.g., chart notes) documenting that hormone deficiency is a result of hypothalamic-pituitary disease from organic or known causes (e.g., damage from surgery, cranial irradiation, head trauma, or subarachnoid hemorrhage)</p>	

AND

2 - One of the following: [10, 12, 21]

2.1 Both of the following:

2.1.1 Patient has undergone one of the following GH stimulation tests to confirm adult GH deficiency:

- Insulin tolerance test (ITT)
- Glucagon
- Macimorelin

AND

2.1.2 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 Both of the following:

2.2.1 Submission of medical records (e.g., chart notes) documenting deficiency of three of the following anterior pituitary hormones:

- Prolactin
- ACTH
- TSH
- FSH/LH

AND

2.2.2 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Genotropin, Humatrope, Saizen, Zomacton [B, 21]

Diagnosis | Adult Growth Hormone Deficiency

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes

Use the following criteria for child- and adult-onset with pituitary disease; use Isolated GHD in Adult criteria for patients without pituitary disease.

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope* [off-label]

Diagnosis	Transition Phase Adolescent Patients
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope* [off-label]

Diagnosis Transition Phase Adolescent Patients

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton

Diagnosis Transition Phase Adolescent Patients [off-label] [B]

Approval Length 12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - One of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L

- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton

Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton

Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type

Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following: [21]

- Attained expected adult height
- Closed epiphyses on bone radiograph

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following: [20, 21]

2.1 Both of the following:

2.1.1 Documentation of high risk of GH deficiency due to GH deficiency in childhood from one of the following:

2.1.1.1 Embryopathic/congenital defects

OR

2.1.1.2 Genetic mutations

OR

2.1.1.3 Irreversible structural hypothalamic-pituitary disease

OR

2.1.1.4 Panhypopituitarism

OR

2.1.1.5 Deficiency of three of the following anterior pituitary hormones:

- ACTH
- TSH
- Prolactin
- FSH/LH

AND

2.1.2 One of the following:

2.1.2.1 IGF-1/Somatomedin-C level is below the age and gender adjusted normal range as provided by the physician's lab

OR

2.1.2.2 All of the following:

2.1.2.2.1 Patient does not have a low IGF-1/Somatomedin C level

AND

2.1.2.2.2 Discontinued GH therapy for at least 1 month

AND

2.1.2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.1.2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L

- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

OR

2.2 All of the following:

2.2.1 At low risk of severe GH deficiency (e.g., due to isolated and/or idiopathic GH deficiency)

AND

2.2.2 Discontinued GH therapy for at least 1 month

AND

2.2.3 Patient has undergone one of the following GH stimulation tests after discontinuation of therapy for at least 1 month:

- ITT
- Glucagon
- Macimorelin

AND

2.2.4 Patient has one of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Evidence of positive response to therapy (e.g., increase in total lean body mass, exercise capacity or IGF-1 and IGFBP-3 levels)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p> <ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]</p> <p>1.1 Patient has undergone two of the following GH stimulation tests:</p> <ul style="list-style-type: none"> • ITT • Glucagon • Macimorelin <p style="text-align: center;">AND</p> <p>1.2 Patient has two of the following corresponding peak GH values:</p> <ul style="list-style-type: none"> • ITT less than or equal to 5 mcg/L • Glucagon less than or equal to 3 mcg/L • Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p>	
Notes	*Approve at NDC list "SOMATROPPIA".

Product Name: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes

*Approve at NDC list "SOMATROPPIA".

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [off-label] [B, 21]

Diagnosis | Isolated Growth Hormone Deficiency in Adults

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Documented deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Sogroya, Zomacton [off-label] [B, 21]

Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Evidence of ongoing monitoring as demonstrated by documentation within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21]

Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting deficiency of GH as demonstrated by both of the following: [20-21]

1.1 Patient has undergone two of the following GH stimulation tests:

- ITT
- Glucagon
- Macimorelin

AND

1.2 Patient has two of the following corresponding peak GH values:

- ITT less than or equal to 5 mcg/L
- Glucagon less than or equal to 3 mcg/L
- Macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 minutes following macimorelin administration

AND

2 - Prescribed by or in consultation with an endocrinologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Product Name: Genotropin, Humatrope, Saizen, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting evidence of ongoing monitoring within the past 12 months of an IGF-1/Somatomedin C level [10, 12, 21]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an endocrinologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to one of the following: [B]</p> <ul style="list-style-type: none"> • Norditropin (somatropin) • Nutropin (somatropin) • Omnitrope (somatropin) 	

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of HIV-associated wasting syndrome or cachexia [7, 15, 18, 19]</p>	

AND

2 - One of the following: [7, 15, 18, 19, C]

2.1 Unintentional weight loss of greater than 10% over the last 12 months

OR

2.2 Unintentional weight loss of greater than 7.5% over the last 6 months

OR

2.3 Loss of 5% body cell mass (BCM) within 6 months

OR

2.4 Body mass index (BMI) less than 20 kg/m²

OR

2.5 All of the following

- Patient is male
- BCM less than 35% of total body weight
- BMI less than 27 kg/m²

OR

2.6 All of the following

- Patient is female
- BCM less than 23% of total body weight
- BMI less than 27 kg/m²

AND

3 - Nutritional evaluation since onset of wasting first occurred [7, 15, 18, 19]

AND

4 - Patient has not had weight loss as a result of other underlying treatable conditions (e.g., depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes) [7, 15, 18, 19]

AND

5 - Anti-retroviral therapy has been optimized to decrease the viral load [7, 15, 18, 19]

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	6 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Evidence of positive response to therapy (i.e., greater than or equal to 2% increase in body weight and/or BCM) [17, 18]	
AND	
2 - One of the following targets or goals has not been achieved: [17, 18]	
<ul style="list-style-type: none">• Weight• BCM• BMI	

Product Name: Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	4 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Short Bowel Syndrome [9, 16]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements) [9, 16]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has not previously received 4 weeks of treatment with Zorbtive [9, 16]</p>	
Notes	NOTE: Treatment with Zorbtive will not be authorized beyond 4 weeks . Administration for more than 4 weeks has not been adequately studied.

Product Name: All Products	
Guideline Type	Prior Authorization, Non Formulary
<p>Approval Criteria</p> <p>1 - Requests for coverage of growth hormone for the diagnosis of Idiopathic Short Stature (ISS) are not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the indications, efficacy, safety, or long-term consequences of GH therapy in children with ISS who are otherwise healthy. [E]</p>	
Notes	Approval Length: N/A - Requests for non-approvable diagnoses should not be approved

3 . Endnotes

- A. Several recent review articles in the literature have suggested that GH stimulation tests should no longer be used to diagnose GHD. [13,14] The authors argue that GH stimulation test may have side effects, lack precision, accuracy, and do not predict response to GH therapy. It has been suggested that newer diagnostic procedures such as serum IGF-1, IGFBP-3 concentrations, genetic testing and neuroimaging could provide an alternative approach to the diagnosis of GHD in childhood.
- B. Overall, there are no observable differences in the results obtained among the different preparations as long as the regimen follows currently approved daily injections. Many of the products are available in a variety of injection devices that are meant to make administration more appealing and easier. Currently, there is no evidence that clinical outcome differs among the various injection systems, although there may be patient and parent preferences for some of these devices. [11, 21]
- C. Even a 5% weight loss in persons with HIV infection indicates a poor prognosis. [2]
- D. Patients with HIV-associated wasting may begin an initial 12-week course of therapy with Serostim, 6 mg/day s.c. The clinician should monitor treatment responses by obtaining serial body weights and BCM measurements by BIA. A positive response to therapy probably should be considered as a 2% increase in body weight and/or BCM. Maintenance therapy may continue on a monthly basis as long as wasting is still evident. Once BCM has normalized, therapy can be stopped, with the patient being observed for an 8-week period. Over these 8 weeks, body weight, BCM, and any appearance of wasting symptoms can be monitored. If wasting reappears, therapy can be restarted. [17]
- E. Guidelines for idiopathic short stature recommend against the routine use of GH in every child with height standard deviation score $\leq - 2.25$. [23]
- F. When GHD is congenital and near complete, the diagnosis is relatively easy to confirm because affected children present with severe growth failure, delayed bone age, and very low serum concentrations of GH, IGF-1, and IGFBP-3 [8]. For patients with all of these clinical characteristics, it is reasonable to make the diagnosis of GHD without performing GH stimulation testing. [29]
- G. Measurements of IGF-1 and IGFBP-3 have shown comparable diagnostic performance with growth hormone stimulation tests and are valuable for patient's convenience and ease of performance and can be useful in the workup of growth hormone deficiency. [30]

4 . References

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H.P. Acthar Gel (repository corticotropin)

Prior Authorization Guideline

Guideline Name	H.P. Acthar Gel (repository corticotropin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: H.P. Acthar Gel	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of infantile spasms (West Syndrome) AND 2 - Prescribed by or in consultation with a neurologist	

AND

3 - Patient is less than 2 years of age

Product Name: H.P. Acthar Gel

Diagnosis	Multiple Sclerosis
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Approval Length	3 Week(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Trial and failure, contraindication, or intolerance to treatment with two corticosteroids (e.g., prednisone, methylprednisolone)

Product Name: H.P. Acthar Gel

Diagnosis	All Other Indications [A]
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Approval Length	0 N/A - Requests for non-approvable diagnoses should not be approved
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Guideline Type	Prior Authorization
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Approval Criteria

1 - The request for H.P. Acthar for the treatment of a condition other than Infantile Spasms

(IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

- Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.
- Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
- Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.
- Allergic States* [A] Serum sickness.
- Ophthalmic Diseases* [A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.
- Respiratory Diseases* [11, A] Symptomatic sarcoidosis.
- Edematous State* [12, 13, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Any other disease state not mentioned [A]*

Notes

*Other disease states lack published clinical literature to support the use of H.P. Acthar. [A]

2 . Endnotes

- A. Grandfathered indications, although briefly mentioned in the labeling, do not have clinical studies in the prescribing information or medical literature supporting their use of HP Acthar.

3 . References

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Prior Authorization Guideline

Guideline Name	Harvoni (ledipasvir/sofosbuvir) - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Harvoni (ledipasvir/sofosbuvir)
Chronic Hepatitis C Indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV): - Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; - Genotype 1 infection with decompensated cirrhosis, for use in combination with ribavirin; - Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, for use in combination with ribavirin

2 . Criteria

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient is without cirrhosis

AND

3 - Patient is treatment-naive

AND

4 - Pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.
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Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA less than 6 Million IU/mL
Approval Length	8 Week(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1</p> <p style="text-align: center;">AND</p> <p>2 - Patient is without cirrhosis</p> <p style="text-align: center;">AND</p>	

3 - Patient is treatment-naive

AND

4 - Submission of medical records documenting pre-treatment HCV RNA less than 6 million IU/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and

failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis - Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C genotype 1	
AND	
2 - Patient is without cirrhosis	
AND	
3 - Patient is treatment-naive	
AND	
4 - Pre-treatment HCV RNA greater than or equal to 6 million IU/mL	
AND	
5 - Prescribed by or in consultation with one of the following:	

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

7 - One of the following (applies to brand ledipasvir/sofosbuvir only):

7.1 Both of the following:

7.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes

*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir

Diagnosis

Chronic Hepatitis C - Genotype 1 - Treatment Naive without Cirrhosis
- Pre-Treatment HCV RNA greater than or equal to 6 Million IU/mL

Approval Length

12 Week(s)

Guideline Type	Non Formulary
<p data-bbox="196 352 438 384">Approval Criteria</p> <p data-bbox="196 422 1289 485">1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1</p> <p data-bbox="773 558 841 590" style="text-align: center;">AND</p> <p data-bbox="196 663 578 695">2 - Patient is without cirrhosis</p> <p data-bbox="773 768 841 800" style="text-align: center;">AND</p> <p data-bbox="196 873 570 905">3 - Patient is treatment-naive</p> <p data-bbox="773 978 841 1010" style="text-align: center;">AND</p> <p data-bbox="196 1083 1338 1146">4 - Submission of medical records documenting pre-treatment HCV RNA greater than or equal to 6 million IU/mL</p> <p data-bbox="773 1220 841 1251" style="text-align: center;">AND</p> <p data-bbox="196 1325 976 1356">5 - Prescribed by or in consultation with one of the following:</p> <ul data-bbox="245 1398 1211 1524" style="list-style-type: none">• Hepatologist• Gastroenterologist• Infectious disease specialist• HIV specialist certified through the American Academy of HIV Medicine <p data-bbox="773 1598 841 1629" style="text-align: center;">AND</p> <p data-bbox="196 1703 1325 1766">6 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])</p>	

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir

Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
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Approval Length	12 Week(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)

- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.
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Product Name: Brand ledipasvir/sofosbuvir

Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 - Treatment-Naive or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced (No Decompensated Cirrhosis)
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6

AND

2 - One of the following:

- Patient is treatment-naive
- Patient has prior failure to peginterferon alfa plus ribavirin treatment
- Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6</p> <p style="text-align: center;">AND</p> <p>2 - Patient is a liver transplant recipient</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)</p> <p style="text-align: center;">OR</p> <p>3.2 Both of the following:</p> <ul style="list-style-type: none">• Patient has decompensated cirrhosis (Child-Pugh Class B or C)• Used in combination with ribavirin <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Hepatologist• Gastroenterologist	

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following (applies to brand ledipasvir/sofosbuvir only):

6.1 Both of the following:

6.1.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior brand ledipasvir/sofosbuvir

Notes	*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.
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Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Post-Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Patient is a liver transplant recipient

AND

3 - One of the following:

3.1 Patient is without cirrhosis or has compensated cirrhosis (Child-Pugh Class A)

OR

3.2 Both of the following:

- Patient has decompensated cirrhosis (Child-Pugh Class B or C)
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6	
AND	

2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Trial and failure, contraindication, or intolerance to ONE of the following (applies to brand ledipasvir/sofosbuvir only):

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Notes

*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis - Ribavirin Eligible
Approval Length	12 Week(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Product Name: Harvoni*, Brand ledipasvir/sofosbuvir	
Diagnosis	Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6</p> <p style="text-align: center;">AND</p> <p>2 - Patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Patient is ribavirin ineligible</p> <p style="text-align: center;">OR</p> <p>3.2 Both of the following:</p> <ul style="list-style-type: none"> • Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy • Used in combination with ribavirin <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist 	

- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Trial and failure, contraindication, or intolerance to ONE of the following (applies to brand ledipasvir/sofosbuvir only):

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

Notes

*Approve brand Harvoni at NDC level (i.e., closed NDC) if criteria are met.

Product Name: Brand ledipasvir/sofosbuvir

Diagnosis

Chronic Hepatitis C - Genotype 1, 4, 5, or 6 – Decompensated Cirrhosis; Ribavirin Ineligible OR Prior Sovaldi or NS5A-Based Treatment Failure

Approval Length

24 Week(s)

Guideline Type

Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has decompensated cirrhosis (e.g., Child-Pugh Class B or C)

AND

3 - One of the following:

3.1 Patient is ribavirin ineligible

OR

3.2 Both of the following:

- Prior failure (defined as viral relapse, breakthrough while on therapy, or non-responder therapy) to Sovaldi or NS5A-based therapy
- Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent (e.g., Sovaldi [sofosbuvir])

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to **ONE** of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

3 . References

1. Harvoni Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Prior Authorization Guideline

Guideline Name	Healthcare Reform Copay Waiver Review
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Guideline Note:

Effective Date:	1/20/2024
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Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name: Fluoride supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	
1 - Patient is between 6 months of age to 16 years of age**	

AND

2 - Requested product is a prescription (single ingredient only) oral fluoride supplementation product (does not include topical fluoride products such as toothpaste or rinses, etc.)

AND

3 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list* (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes

*The HCR preventive drug list is posted at: <http://app37-02.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document>. **Benefit exclusion if age not met.

Product Name: Folic acid supplementation products

Approval Length

12 month(s)

Guideline Type

Administrative

Approval Criteria

1 - Patient is of childbearing potential who is planning pregnancy**

AND

2 - Requested product is a prescription or OTC folic acid product (with prescription), including prenatal vitamins containing folic acid**

AND

3 - Requested product contains between 0.4 mg to 0.8 mg of folic acid***

AND

4 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list* (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)

Notes

*The HCR preventive drug list is posted at: <http://app37-02.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document>. ** Benefit exclusion if not for childbearing or for multivitamins without folic acid. ***Greater than 0.8mg is allowed for medical necessity

Product Name: Smoking Cessation products

Approval Length

6 months per 12 months for zero copay with deductible bypass

Guideline Type

Administrative

Approval Criteria

1 - Patient is 18 years of age or older*

AND

2 - For use as an aid to smoking cessation treatment*

AND

3 - Any requested HCR \$0 Rx or OTC smoking cessation product and quantity requested does not exceed the following quantities:

- Maximum of 180 days of therapy per year for all tobacco cessation products
- Brand or Generic Chantix: starter kits limited to one 53 tablet starter kit; Maximum Daily Dose (MDD) = 2 units per day for remainder of therapy
- Nicotrol NS: MDD = 4 mL per day
- Nicotrol Inhaler: MDD = 16 units per day
- Zyban/Buproban/bupropion 150 mg SR: MDD = 2
- Brand or Generic OTC Nicotine replacement patch: MDD = 1
- Brand or Generic OTC Nicotine replacement gum: MDD = 24
- Brand or Generic OTC Nicotine replacement lozenge: MDD = 20

AND

4 - If request is for Nicotrol inhaler or Nicotrol NS, a history of both of the following:

4.1 Generic Zyban (bupropion)

AND

4.2 One of the following smoking cessation therapies:

- Nicotine gum
- Nicotine lozenge
- Nicotine transdermal patch

AND

5 - If request is for brand Chantix, member has had a trial and failure, contraindication, or intolerance to generic varenicline

Notes

*Benefit exclusion if age not met or not used for smoking cessation or used beyond 180 days.

Product Name: Contraceptives [E]

Approval Length

12 month(s)

Guideline Type

Administrative

Approval Criteria

1 - For medical necessity requests, to waive cost-sharing for a medication not included on a zero-cost-sharing coverage list* BOTH of the following must be met:

1.1 Patient is using the prescribed drug for contraception**

AND

1.2 The requested product is medically necessary***:

Notes

*FDA Contraceptive Methods available at: <https://www.fda.gov/consumers/free-publications-women/birth-control>. **Benefit exclusion if not for contraception. ***Any justification of medical necessity/appropriateness

	ess provided by the prescriber is adequate to approve access of a preferred product at \$0 cost share, in accordance with the ACA's contraceptive mandate
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Product Name: Immunizations	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Requested product is a single-entity or combination vaccination for one of the following:*

- Diphtheria
- Haemophilus influenzae type B (applies only to children less than 6 years of age)***
- Hepatitis A
- Hepatitis B (Hepelisav B applies only to adults ages 18 years and older)***
- Herpes zoster (Shingrix applies to adults ages 19 years and older)***
- Human papillomavirus (applies only to children and adults 9 years to 26 years of age)***
- Polio
- Influenza (Flumist applies only to children and adults 2 years through 49 years of age. Fluzone HD Quad, Fluad Quad applies only to adults ages 65 years and older)***
- Measles
- Mumps
- Rubella
- Meningococcal infections
- Pertussis
- Pneumococcal infections
- Rotavirus (applies only to children less than 8 months)***
- Tetanus
- Varicella

OR

2 - All of the following:

2.1 Requested product is for Dengue vaccine

AND

2.2 Member is between ages 9-16 living in a dengue endemic area (endemic areas include

Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau)**

AND

2.3 Member has a laboratory confirmation of a previous dengue infection

Notes	<p>*This list excludes vaccines not listed in the Advisory Committee on Immunization Practices (ACIP) Immunization Schedules (http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html).</p> <p>**For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see: https://www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm and https://www.cdc.gov/dengue/vaccine/hcp/index.html</p> <p>***Benefit exclusion if age not met.</p>
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Product Name: Bowel preparation agents for colorectal cancer screening [F]	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Requested product is a prescription bowel preparation agent used for primary preventative colorectal cancer screening (e.g., patient does not have a previous history of adenomatous polyps or previous colorectal cancer)**.</p> <p style="text-align: center;">AND</p> <p>2 - There is a clinical reason why the patient cannot take two generic products on the HCR preventive drug list* (i.e., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response). (Some examples of generic bowel prep products include: TriLyte, Gavilyte, PEG-3350/electrolytes.)</p> <p style="text-align: center;">AND</p> <p>3 - Quantity requested does not exceed the QL of two primary preventive bowel prep product per year***</p>	
Notes	*The HCR preventive drug list is posted at: http://app37-02.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare

	Reform Supporting Document. **Benefit exclusion if not for cancer screening. ***If a patient has an intolerance, allergic reaction, or an inadequate response to one of the products on the HCR preventative drug list, then the quantity limits will not apply for one time only per drug category (to allow for another product to be tried on the HCR preventative drug list).
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Product Name: Arimidex (anastrozole) 1 mg, Aromasin (exemestane) 25 mg, Tamoxifen (20mg tablets), Soltamox (tamoxifen) solution, Evista (raloxifene)

Approval Length	60 Months: Authorization will be issued for zero copay with deductible bypass for up to a total of 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).
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Guideline Type	Administrative
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<p>Approval Criteria</p> <p>1 - Member is greater than or equal to 35 years of age*</p> <p style="text-align: center;">AND</p> <p>2 - Member has no prior diagnosis of any of the following*:</p> <ul style="list-style-type: none"> • breast cancer • ductal carcinoma in situ (DCIS) <p style="text-align: center;">AND</p> <p>3 - Member has no history of thromboembolic events (e.g. - deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)*</p> <p style="text-align: center;">AND</p> <p>4 - Member has an estimated 5 year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3% [11]*</p>	
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AND

5 - One of the following:

5.1 Request is for Tamoxifen 20 mg once daily

OR

5.2 Both of the following:

5.2.1 Member is post-menopausal

AND

5.2.2 One of the following:

5.2.2.1 Request is for raloxifene 60 mg once daily, exemestane 25 mg once daily, or anastrozole 1 mg once daily

OR

5.2.2.2 Request is for Evista 60 mg, Aromasin 25 mg, and Arimidex 1 mg once daily and member has had failure, contraindication or adverse reaction to generic raloxifene, exemestane, or anastrozole

OR

5.3 Both of the following:

5.3.1 Request is for Soltamox 20 mg once daily*

AND

5.3.2 Member has had failure, contraindication or adverse reaction to tamoxifen tablets

Notes	*Benefit exclusion if age not met or has prior cancer diagnosis or has thromboembolic events or less than 3% risk factor or requesting a different strength. This program is designed to meet Health Care Reform requirements which require coverage of tamoxifen tablets, Soltamox (tamoxifen) solution, Evista (raloxifene), Aromasin (exemestane), and Arimidex (anastrozole) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met.
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Product Name: Brand Truvada 200-300 mg, Generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, Brand Viread 300 mg, generic tenofovir disoproxil fumarate 300mg, Descovy	
Approval Length	12 Months. Authorization will be issued for zero copay with deductible bypass for 12 months
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Member is taking as effective antiretroviral therapy for preexposure prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Request is for generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg or generic tenofovir disoproxil fumarate 300 mg</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg (Applies to Brand Truvada 200-300 mg and Descovy only)</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.3 History of contraindication or intolerance to tenofovir disoproxil fumarate 300mg (Applies to Brand Viread 300 mg only)</p>	
Notes	This program is designed to meet Health Care Reform requirements which require coverage of effective HIV PrEP regimens at zero dollar cost share if being used for preexposure prophylaxis (PrEP) and criteria are met.

ia are met. [I] *The HCR preventive drug list is posted at: <http://app37-02.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document>.

2 . Background

Clinical Practice Guidelines

Clinical Practice Guidelines **FDA Contraceptive Methods

**FDA Contraceptives Methods

Items 6-18 pertain to the ORx standard Health Care Reform Benefit

- 1 – Sterilization Surgery
- 2 – Surgical Sterilization Implant for Women
- 3 – Implantable Rod*
- 4 – Copper IUD*
- 5 – IUD with Progestin*
- 6 – Shot/Injection
- 7 – OC, Combined Pill
- 8 – OC, Progestin Only
- 9 – OC, Extended/Continuous use
- 10 – Patch
- 11 – Vaginal Contraceptive Ring
- 12 – Diaphragm
- 13 – Sponge
- 14 – Cervical Cap
- 15 – Female Condom

16 – Spermicide

17 – Emergency Cont., Plan B/Plan B One-Step

18 – Emergency Cont., Ella

** FDA Contraceptive Methods, per FAQ XXVI. <http://www.dol.gov/ebsa/pdf/faq-aca26.pdf>

* Some plans may cover these items through the Pharmacy Benefit. Please consult the Formulary Lookup tool.

Benefit/Coverage/Program Information

Program information

If the patient does not meet the above criteria, then the prescription will not be covered at zero cost-share.

3 . Endnotes

- A. Important Risk Factors for Breast Cancer [5]: (1) Family history of breast or ovarian cancer (especially among first-degree relatives and onset before age 50 years); (2) History of atypical hyperplasia; (3) Non-malignant high-risk breast lesions; (4) Previous breast biopsy; (5) Extremely dense breast tissue; (6) Increasing age; (7) Race or ethnicity; (8) Age at menarche; (9) Age at first live childbirth; (10) Ductal carcinoma in situ (DCIS); (11) Lobular carcinoma in situ (LCIS); (12) Body mass index; (13) Menopause status or age; (14) Estrogen and progestin use; (15) Smoking; (16) Alcohol use; (17) Physical activity; (18) Diet.
- B. The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP] <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html>, Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.
- C. OptumRx has developed a Healthcare Reform Preventative Drug List posted at: <http://optumrx.optum.com/sites/CST/CSDM/Shared Documents/UMCS Guidelines/Healthcare Reform Supporting Document> that identifies which products are eligible for coverage without patient copayment. Some products may be excluded (such as brand oral contraceptives) unless the patient meets the criteria in this exceptions policy.
- D. Here is a brief summary of the exceptions allowed in this policy (provided the patient meets all of the specified criteria): (1) The fluoride supplementation exception allows for brand name products at no cost-share, but not combination products; (2) The folic acid exception allows for brand name and Rx products at no cost-share; (3) The smoking cessation exception allows for Chantix, Nicotrol Inhaler, Nicotrol NS, and brand Zyban at

no cost-share, but not additional quantities beyond the QLs; all other covered tobacco cessation products for members ages 18 years and older and not to exceed listed QLs; (4) The contraceptives exception allows for brand name products at no cost-share but not beyond the QLs; (5) The bowel preparation agent exception allows for brand name Rx products at no cost-share but not beyond the QL.

- E. Oral Contraceptives: In order to receive an oral contraceptive at zero cost-share, a woman must be of childbearing potential and must be requesting an oral contraceptive for contraception (and not for another use) or if provider states medical necessity (as well as meeting the other criteria noted at the beginning of the policy). In addition, the 21 or 28 day oral contraceptive packs should not be approved for continuous use because there are continuous use products already on the Healthcare Reform Preventative Drug List posted at:

<https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document>.

- F. Bowel Preparation Agents: It is important to distinguish between a screening and a surveillance or diagnostic colonoscopy. Screening is performed in asymptomatic patients with no history of colon cancer, polyps, and/or gastrointestinal disease. [1] Whereas, a surveillance colonoscopy can be performed at varying ages and intervals based on the patient's personal history of colon cancer, polyps, and/or gastrointestinal disease. Patients with a history of colon polyp(s) are not recommended for a screening colonoscopy, but for a surveillance colonoscopy. Per the USPSTF, when the screening test results in the diagnosis of clinically significant colorectal adenomas or cancer, the patient will be followed by a surveillance regimen, and recommendations for screening are no longer applicable. [6] According to the USPSTF, routine colorectal cancer screening is now recommended in adults beginning at age 50 and continuing only until age 75. [6] However, an earlier start to screening may be reasonable in patients with first-degree relatives who developed cancer at a younger age or in patients with multiple affected first-degree relatives. The following screening modalities are recommended: high-sensitivity fecal occult blood testing (FOBT), sigmoidoscopy with interval FOBT, or colonoscopy. With this statement, the USPSTF concludes that for computed tomography (CT) colonography and fecal DNA, there is insufficient evidence to permit a recommendation. In March 2008, the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology jointly recommended screening for colorectal cancer beginning at 50 years of age by 1) high-sensitivity FOBT or fecal immunochemical testing annually, 2) flexible sigmoidoscopy every 5 years, 3) double-contrast barium enema every 5 years, 4) CT colonography (virtual colonoscopy) every 5 years, 5) colonoscopy every 10 years, or 6) fecal DNA at an unspecified interval. The American College of Gastroenterology recommends fecal DNA testing every 3 years. Based on the collective information above, we have a quantity limit in place of one bowel preparation agent per year. (This quantity limit will not apply if patient was intolerant to, had an allergic reaction, or an inadequate response to one of the bowel prep products on the HCR preventative drug list.)
- G. Breast Cancer Prevention: The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. [5] For women who are at an increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction of primary breast cancer in women who are not at increased risk for breast cancer. The updated STAR trial results show diminished benefits of raloxifene compared to tamoxifen after cessation of therapy, making it a preferred risk reduction choice for most post-

menopausal women desiring non-surgical risk reduction therapy. However, consideration of toxicity (e.g., endometrial cancer or uterine bleeding) may still lead to the choice of raloxifene over tamoxifen in some women.

- H. The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse medication effects. (B recommendation) The USPSTF recommends against the routine use of risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, in women who are not at increased risk for breast cancer. (D recommendation) This recommendation applies to asymptomatic women 35 years and older, including women with previous benign breast lesions on biopsy (such as atypical ductal or lobular hyperplasia and lobular carcinoma in situ). This recommendation does not apply to women who have a current or previous diagnosis of breast cancer or ductal carcinoma in situ.
- I. I. The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. [19] Once-daily oral treatment with Truvada is the only formulation of PrEP approved by the US Food and Drug Administration (FDA) for use in the United States in persons at risk of sexual acquisition of HIV infection. However, several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP, and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs. [20, 21]

4 . References

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Prior Authorization Guideline

Guideline Name	Hereditary Angioedema Agents
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Berinert (C1 esterase inhibitor [Human])
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of HAE in adult and adolescent patients. The safety and efficacy of Berinert for prophylactic therapy have not been established.
Drug Name: Cinryze (C1 esterase inhibitor [Human])
Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis against angioedema attacks in adults, adolescents and pediatric patients (6 years old and above) with HAE. Off Label Uses: Acute treatment of Hereditary Angioedema (HAE) Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with HAE. [3]
Drug Name: Firazyr (icatibant)
Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of HAE in adults 18 years of age and older.
Drug Name: Haegarda (C1 esterase inhibitor [Human])

Prophylaxis of Hereditary Angioedema (HAE) Indicated for routine prophylaxis to prevent HAE attacks in patients 6 years of age and older.

Drug Name: Kalbitor (ecallantide)

Acute treatment of Hereditary Angioedema (HAE) Indicated for treatment of acute attacks of HAE in patients 12 years of age and older.

Drug Name: Orladeyo (berotralstat)

Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. Limitations of Use: Orladeyo should not be used for treatment of acute HAE attacks.

Drug Name: Ruconest (C1 esterase inhibitor [Recombinant])

Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks in adult and adolescent patients with HAE. Limitation of Use: Effectiveness was not established in HAE patients with laryngeal attacks.

Drug Name: Takhzyro (lanadelumab-flyo)

Prophylaxis of Hereditary Angioedema (HAE) Indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.

2 . Criteria

Product Name: Cinryze, Haegarda, Orladeyo, or Takhzyro	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hereditary angioedema (HAE) [A]	
AND	

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by ONE of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze and Haegarda only)
- Patient is 12 years of age or older (applies to Orladeyo only)
- Patient is 2 years of age or older (applies to Takhzyro only)

AND

5 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Cinryze [off-label], Brand Firazyr, Generic icatibant, Sajazir, or Ruconest	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hereditary angioedema (HAE) [3, A]	

AND

2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:

- C1-INH antigenic level below the lower limit of normal
- C1-INH functional level below the lower limit of normal

AND

3 - For the treatment of acute HAE attacks [3, C]

AND

4 - Not used in combination with other approved treatments for acute HAE attacks

AND

5 - One of the following:

- Patient is 6 years of age or older (applies to Cinryze only)
- Patient is 18 years of age or older (applies to Brand Firazyr, generic icatibant, and Sajazir only)

AND

6 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

AND

7 - Trial and failure or intolerance to generic icatibant (applies to brand Firazyr only)

Product Name: Kalbitor	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hereditary angioedema (HAE) [A]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:</p> <ul style="list-style-type: none"> • C1-INH antigenic level below the lower limit of normal • C1-INH functional level below the lower limit of normal <p style="text-align: center;">AND</p> <p>3 - For the treatment of acute HAE attacks</p> <p style="text-align: center;">AND</p> <p>4 - Patient is greater than or equal to 12 years of age [D]</p> <p style="text-align: center;">AND</p> <p>5 - Not used in combination with other approved treatments for acute HAE attacks</p> <p style="text-align: center;">AND</p> <p>6 - Prescribed by or in consultation with one of the following: [B]</p> <ul style="list-style-type: none"> • Immunologist 	

- Allergist

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hereditary angioedema (HAE) [3, A]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following:</p> <ul style="list-style-type: none"> • C1-INH antigenic level below the lower limit of normal • C1-INH functional level below the lower limit of normal <p style="text-align: center;">AND</p> <p>3 - For the treatment of acute HAE attacks [3, C]</p> <p style="text-align: center;">AND</p> <p>4 - Not used in combination with other approved treatments for acute HAE attacks</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following: [B]</p> <ul style="list-style-type: none"> • Immunologist • Allergist 	

3 . Endnotes

- A. HAE is a rare genetic disorder caused by a deficiency of C1-inhibitor and is inherited in an autosomal dominant manner. This condition is characterized by recurrent episodes of angioedema, without urticaria or pruritus, which most often affect the skin or mucosal tissues of the upper respiratory and gastrointestinal tracts. Diagnosis of HAE requires a blood test to confirm low or abnormal levels of C1-inhibitor. [10]
- B. Includes immunologist, allergist and rheumatologist specialties to ensure the requirement for proper diagnosing and assessing the severity of the symptoms. In the pivotal Cinryze trial, criteria for participation of long term prophylaxis included patients 9 years and older with documented HAE (based on: a low C4 level plus low C1 inhibitor antigenic level/or low C1 inhibitor functional level OR a known HAE causing mutation) AND a history of at least two HAE attack per month. [1, 8] Berinert is approved for the treatment of acute attacks in patients who are 13 years and older. In the pivotal Berinert trial patients had laboratory-confirmed C1-inhibitor deficiency (type I or II HAE). [9]
- C. Following treatment with nanofiltered C1 inhibitor concentrate (Cinryze) for an acute attack, the median time to response was 30 minutes in 82 patients with hereditary angioedema (median number of attacks per patient, 3; range, 1 to 57 attacks) in an open-label extension trial (median follow-up of 11 months). Additionally, 93% of attacks responded within 4 hr after C1 inhibitor concentrate treatment. [3]
- D. Kalbitor carries a black box warning that states the following: "Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, Kalbitor should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and hereditary angioedema (HAE). Healthcare professionals should be aware of the similarity of symptoms between hypersensitivity reactions and hereditary angioedema and patients should be monitored closely. Do not administer Kalbitor to patients with known clinical hypersensitivity to Kalbitor." In 255 HAE patients treated with intravenous or subcutaneous Kalbitor in clinical studies, 10 patients (3.9%) experienced anaphylaxis. For the subgroup of 187 patients treated with subcutaneous Kalbitor, 5 patients (2.7%) experienced anaphylaxis. Symptoms associated with these reactions have included chest discomfort, flushing, pharyngeal edema, pruritus, rhinorrhea, sneezing, nasal congestion, throat irritation, urticaria, wheezing, and hypotension. These reactions occurred within the first hour after dosing. Other adverse reactions indicative of hypersensitivity reactions included the following: pruritus (5.1%), rash (3.1%), and urticaria (2.0%). Patients should be observed for an appropriate period of time after administration of Kalbitor, taking into account the time to onset of anaphylaxis seen in clinical trials. In the Kalbitor HAE program, patients developed antibodies to ecallantide. Rates of seroconversion increased with exposure to ecallantide over time. Overall, 7.4% of patients seroconverted to anti-ecallantide antibodies. Neutralizing antibodies to ecallantide were determined in vitro to be present in 4.7% of patients. Anti-ecallantide and anti-*Po pastoris* IgE antibodies were also detected. While the long-term effects of antibodies to Kalbitor are not known, patients who seroconvert may be at a higher risk of a hypersensitivity reaction. The manufacturer developed a Risk Evaluation and Mitigation Strategy (REMS) program consisting of a Medication Guide and Communication Plan to notify healthcare professionals of the risk of anaphylaxis and the need to distinguish signs and symptoms of anaphylaxis and HAE attack as they may overlap. The presence of the black box warning necessitating

administration by a healthcare professional; development of antibodies to ecallantide that may predispose patients to higher risks of hypersensitivity reactions; and the requirement for a REMS program offer compelling evidence to warrant the continued inclusion of an age criterion. [7]

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Prior Authorization Guideline

Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Hetlioz (tasimelteon) capsule
Non-24-Hour Sleep-Wake Disorder (Non-24) Indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24) in adults.
Smith-Magenis Syndrome (SMS) Indicated for the treatment of nighttime sleep disturbances in SMS in patients 16 years of age and older.
Drug Name: Hetlioz LQ (tasimelteon) suspension
Smith-Magenis Syndrome (SMS) Indicated for the treatment of nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in pediatric patients 3 to 15 years of age.

2 . Criteria

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome) [2, 5-6, A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is totally blind (has no light perception) [2-8, B]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Specialist in sleep disorders • Neurologist 	

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule	
Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of positive clinical response to therapy

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule

Diagnosis Smith-Magenis Syndrome (SMS)

Approval Length 6 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 16 years of age or older

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

5 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Smith-Magenis Syndrome (SMS)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 3 through 15 years of age</p> <p style="text-align: center;">AND</p> <p>3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Specialist in sleep disorders • Neurologist 	

Product Name: Brand Hetlioz capsule, generic tasimelteon capsule, Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in nighttime total sleep time, improvement in nighttime sleep quality)

Product Name: Hetlioz capsule

Diagnosis	Non-24-Hour Sleep-Wake Disorder (Non-24)
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Approval Length	6 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernycthemeral syndrome) [2, 5-6, A]

AND

2 - Patient is totally blind (has no light perception) [2-8, B]

AND

3 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

Product Name: Hetlioz capsule

Diagnosis	Smith-Magenis Syndrome (SMS)
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Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Smith-Magenis Syndrome (SMS)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 16 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to generic tasimelteon (Applies to Brand only)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Specialist in sleep disorders • Neurologist 	

Product Name: Hetlioz LQ suspension	
Diagnosis	Smith-Magenis Syndrome (SMS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Smith-Magenis Syndrome (SMS)

AND

2 - Patient is 3 through 15 years of age

AND

3 - Patient is experiencing nighttime sleep disturbances (i.e., difficulty falling asleep, frequent nighttime waking and early waking)

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist in sleep disorders
- Neurologist

3 . Endnotes

- A. The International Classification of Sleep Disorders (an official publication of the American Academy of Sleep Medicine) defines non-24-hour sleep-wake disorder as a circadian rhythm sleep disorder characterized by complaints of insomnia or excessive sleepiness related to abnormal synchronization between the 24-hour light-dark cycle and the endogenous circadian rhythms of sleep and wake propensity, for a duration of 3 months. [2] Patients with non-24 experience a chronic steady pattern comprising 1- to 2-hour daily delays in sleep onset and wake times. As incremental phase delays in sleep occur, the complaint will consist of difficulty initiating sleep at night coupled with oversleeping into the daytime hours or inability to remain awake in the daytime. Therefore, over long periods of time, patients alternate between being symptomatic and asymptomatic, depending on the degree of synchrony between their internal biologic rhythm and the 24-hour world. [2] The condition is very rare in normally sighted people, but quite common in the totally blind who have no access to the entraining effects of the light-dark cycle. [3] Of the estimated 1.3 million legally blind individuals in the United States, approximately 130,000 have no light perception. Epidemiologic studies have

found that as many as 70% of this totally blind sub-population suffer from non-24. [4] Non-24 is considered a chronic condition and markedly decreases the quality of life for patients. To varying extents, individuals with non-24 are unable to function in scheduled social activities or hold conventional jobs. [2, 4]

- B. Hetlioz was approved on the basis of two pivotal, randomized, double-masked, placebo-controlled, multicenter, parallel-group studies in totally blind patients with non-24-hour sleep-wake disorder. [1, 7] The Safety and Efficacy of Tasimelteon (SET) Trial [1,7] was conducted in 84 totally blind patients with non-24, aged 21-84 years. Subjects received either Hetlioz 20 mg or placebo, one hour prior to bedtime, at the same time every night for up to 6 months. The Randomized-withdrawal study of the Efficacy and Safety of Tasimelteon to treat non-24 (RESET) Trial [1,8] was conducted in 20 entrained totally blind patients with non-24, aged 28-70 years. Subjects were treated for approximately 12 weeks with Hetlioz 20 mg one hour prior to bedtime, at the same time every night. Patients in whom the calculated time of peak melatonin level (melatonin acrophase) occurred at approximately the same time of day (in contrast to the expected daily delay) during the run-in phase were randomized to receive placebo or continue treatment with Hetlioz 20 mg for 8 weeks.
- C. Given the wide range of available dosing regimens for melatonin, the variability in response time to treatment with tasimelteon and melatonin, and the need for consistent monitoring and evaluation of patients' sleep-related symptoms, tasimelteon must be prescribed by or in consultation with a specialist in sleep disorders. [3]

4 . References

1. Hetlioz Prescribing Information. Vanda Pharmaceuticals, Inc. Washington D.C. December 2020.
2. International Classification of Sleep Disorders. 3rd ed. Darien, IL: American academy of sleep medicine; 2014.
3. Sack RL, Auckley D, Auger RR, et al. Circadian rhythm sleep disorders: Part II, advanced sleep phase disorder, delayed sleep phase disorder, free-running disorder, and irregular sleep-wake rhythm. *Sleep* 2007;30(11):1484-1501.
4. Vanda Pharmaceuticals, Inc. About Non-24. Available at: <http://www.non-24.com/about-non-24.php>. Accessed September 27, 2017.
5. National Sleep Foundation. Non-24-hour Sleep Wake Disorder Facts and Prevalence. Available at: <https://www.sleepfoundation.org/non-24-sleep-wake-disorder/treatment-care>. May 13, 2022. Accessed June 16, 2022.
6. Circadian Sleep Disorders Network. Non-24-Hour Sleep-Wake Disorder Questions and Answers. Available at: <http://www.circadiansleepdisorders.org/docs/N24-QandA.php>. Accessed September 27, 2017.
7. Lockley SW, Dressman MA, Xiao C, et al. Tasimelteon treatment entrains the circadian clock and demonstrates a clinically meaningful benefit in totally blind individuals with non-24-hour circadian rhythms [Poster abstract no. FP26-6]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.
8. Lockley SW, Dressman MA, Xiao C, Licamele L, Polymeropoulos MH. RESET study demonstrates that tasimelteon maintains entrainment of melatonin and cortisol in totally blind individuals with non-24-hour circadian rhythms [Poster abstract no. SUN-137]. 95th Annual Meeting of the Endocrine Society; 15-18 Jun 2013; San Francisco, CA.

9. National Organization for Rare Disorders. Non-24-Hour Sleep-Wake Disorder Available at: <https://rarediseases.org/rare-diseases/non-24-hour-sleep-wake-disorder/> Accessed June 16, 2022.

Horizant (gabapentin enacarbil)

Prior Authorization Guideline

Guideline Name	Horizant (gabapentin enacarbil)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Horizant	
Diagnosis	Restless Legs Syndrome (RLS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of moderate-to-severe primary restless legs syndrome (RLS) AND 2 - Trial and failure, contraindication, or intolerance to one of the following [A]:	

- ropinirole
- pramipexole

Product Name: Horizant	
Diagnosis	Restless Legs Syndrome (RLS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced an improvement in RLS disease symptoms (e.g., decrease in symptom onset or severity, improved sleep, or decrease in symptom intensity)</p>	

Product Name: Horizant	
Diagnosis	Postherpetic Neuralgia (PHN)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of postherpetic neuralgia (PHN)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [B]:</p> <p> 2.1 Patient has tried and had an inadequate response to a dose of at least 1800 mg of generic gabapentin</p>	

OR

2.2 History of intolerance to generic gabapentin

Product Name: Horizant	
Diagnosis	Postherpetic Neuralgia (PHN)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has experienced an improvement in PHN disease symptoms (e.g., decrease in pain severity)	

2 . Endnotes

- A. Dopamine agonists (such as ropinirole, pramipexole) are the most extensively studied and used therapies for the treatment for daily RLS symptoms. Clinicians can treat patients with levodopa with a dopa decarboxylase inhibitor, opioids, or Horizant (gabapentin enacarbil). Cabergoline can be used if other recommended agents have provided an inadequate response, due to the risk of potential side effects including heart valve damage. Other pharmacologic options include gabapentin, Lyrica (pregabalin), carbamazepine, or clonidine. [2, 3]
- B. While Horizant (gabapentin enacarbil) may improve patient convenience (twice daily rather than three times daily dosing), generic gabapentin is a more well-established, cost-effective therapy for PHN. The use of Horizant (gabapentin enacarbil) should be reserved for patients who have experienced treatment failure or intolerance to generic gabapentin. [4, 5]

3 . References

1. Horizant prescribing information. Arbor Pharmaceuticals; Atlanta, GA. October 2016.
2. Aurora RN, Kristo DA, Bista SR, Rowley JA, Zak RS, Casey KR, et al. The treatment of restless legs syndrome and periodic limb movement disorder in adults – an update for

- 2012: practice parameters with an evidence-based systematic review and meta-analyses. *Sleep*. 2012;35(8):1039-1062.
3. Winkelman JW, Armstrong MJ, Allen RP, et al. Practice guideline summary: Treatment of restless legs syndrome in adults. *Neurology*. 2016;87(24):2585-93.
 4. Attal N, Cruccu G, Baron R, et al. EFNS guidelines on the pharmacological treatment of neuropathic pain: 2010 revision. *Eur J of Neurol*. 2010;17:1113–1123.
 5. Johnson RW and Rice ASC. Postherpetic neuralgia. *N Engl J Med*. 2014;371:1526-33.

Prior Authorization Guideline

Guideline Name	Hydroxyprogesterone caproate injection products
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Makena (hydroxyprogesterone caproate injection)
Reduce Risk of Preterm Birth Indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered less than 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity. Limitation of use: While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.
Drug Name: Hydroxyprogesterone caproate injection (for non-pregnant women)
Amenorrhea Indicated in non-pregnant women for the management of amenorrhea (primary and secondary) and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as submucous fibroids or uterine cancer.
Production of secretory endometrium and desquamation Indicated in non-pregnant women for the production of secretory endometrium and desquamation.
Adenocarcinoma of uterine corpus Indicated in non-pregnant women for the treatment of advanced (Stage III or IV) adenocarcinoma of the uterine corpus.

Test for endogenous estrogen production Indicated as a test for endogenous estrogen production in nonpregnant women.

2 . Criteria

Product Name: Brand Makena, Generic Hydroxyprogesterone 250mg/mL caproate injection	
Diagnosis	Reduce Risk of Preterm birth
Approval Length	21 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient had a previous singleton (single offspring) spontaneous preterm birth</p> <p style="text-align: center;">AND</p> <p>2 - Patient is having a singleton pregnancy</p> <p style="text-align: center;">AND</p> <p>3 - Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation</p> <p style="text-align: center;">AND</p> <p>4 - Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Gynecologist	

- Obstetrician

AND

6 - Provider attests and is aware of the FDA's advisory committee recommendation to withdraw medication due to lack of efficacy shown in post-market data

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)

Diagnosis	Amenorrhea, Abnormal uterine bleeding
Approval Length	4 Month [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Primary or secondary amenorrhea
- Abnormal uterine bleeding

AND

2 - Amenorrhea or abnormal uterine bleeding is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer)

AND

3 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or its generic.
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Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)

Diagnosis	Production of secretory endometrium and desquamation
Approval Length	12 month(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used for production of secretory endometrium and desquamation</p> <p style="text-align: center;">AND</p> <p>2 - Patient is not pregnant</p>	
Notes	Note: This product and its criteria do NOT apply to brand Makena or its generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus</p> <p style="text-align: center;">AND</p> <p>2 - Patient is not pregnant</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist</p>	
Notes	Note: This product and its criteria do NOT apply to brand Makena or its generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Adenocarcinoma of uterine corpus
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p> <p style="text-align: center;">AND</p> <p>2 - Patient is not pregnant</p>	
Notes	Note: This product and its criteria do NOT apply to brand Makena or its generic.

Product Name: Hydroxyprogesterone 1.25g/5mL caproate injection (For Non-Pregnant Women)	
Diagnosis	Test for endogenous estrogen production
Approval Length	2 Month [C]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used for the testing of endogenous estrogen production</p> <p style="text-align: center;">AND</p> <p>2 - Patient is not pregnant</p>	
Notes	Note: This product and its criteria do NOT apply to brand Makena or its generic.

3 . Definitions

Definition	Description
Singleton spontaneous preterm birth	Delivery at less than 37 weeks of gestation following spontaneous preterm labor or premature rupture of membranes. [1]

4 . Endnotes

- A. Pregnant women with a history of preterm birth may benefit from initiating Makena therapy later than the FDA-recommended initiation period (between 16 weeks, 0 days and 20 weeks, 6 days gestation). There are no significant safety concerns with late initiation of therapy. Available evidence suggests it would be reasonable to allow initiation as late as 26 weeks, 6 days. [1-5]
- B. Hydroxyprogesterone caproate injection (for non-pregnant women) for amenorrhea can be given as a one-time dosage or as cyclic therapy as part of a 28-day cycle, with each cycle repeated every 4 weeks and stopped after 4 cycles. [6]
- C. Hydroxyprogesterone caproate injection (for non-pregnant women) for estrogen testing can be started at any time, with a repeat dose given 4 weeks after the first injection for confirmation. Therapy should be stopped after the second injection. [6]

5 . References

1. Makena Prescribing Information. AMAG Pharmaceuticals, Inc. Waltham, MA. February 2018.
2. ACOG Committee Opinion number. Use of progesterone to reduce preterm birth. *Obstet Gynecol.* 2008 Oct;112(4):963-5.
3. Per clinical consult with women's health specialist. May 9, 2011.
4. How HY, Barton JR, Istwan NB, et al. Prophylaxis with 17 alpha-hydroxyprogesterone caproate for prevention of recurrent preterm delivery: does gestational age at initiation of treatment matter? *Am J Obstet Gynecol.* 2007;197(3):260.e1-4.
5. González-Quintero VH, Istwan NB, Rhea DJ, et al. Gestational age at initiation of 17-hydroxyprogesterone caproate (17P) and recurrent preterm delivery. *J Matern Fetal Neonatal Med.* 2007;20(3):249-52.
6. The choice of progestogen for the prevention of preterm birth in women with singleton pregnancy and prior preterm birth. *Am J Obstet Gynecol.* 2017;216(3):B11-B13. doi:10.1016/j.ajog.2017.01.022
7. Hydroxyprogesterone caproate injection Prescribing Information. AuroMedics Pharma LLC. Windsor, NJ. June 2022.
8. Prediction and prevention of spontaneous preterm birth. ACOG Practice Bulletin No. 234. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2021;138:e65–90.

Hyftor (sirolimus) topical gel

Prior Authorization Guideline

Guideline Name	Hyftor (sirolimus) topical gel
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Hyftor (sirolimus) topical gel
Facial Angiofibroma Indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older.

2 . Criteria

Product Name: Hyftor	
Approval Length	4 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of facial angiofibroma associated with tuberous sclerosis complex	

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is not a candidate for laser therapy or surgical treatments

AND

4 - Prescribed by or in consultation with one of the following:

- dermatologist
- neurologist
- geneticist

Product Name: Hyftor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., improvement in size or redness of facial angiofibroma)	

3 . Endnotes

- A. If symptoms do not improve within 12 weeks of treatment, patient should be re-evaluated to determine the need to continue treatment. An additional month is added to the initial authorization duration to allow for patient follow-up with the provider. [1]

4 . References

1. Hyftor Prescribing Information. Nobelpharma America, LLC. Bethesda, MD. March 2022.

HyQvia (immune globulin with recombinant human hyaluronidase)

Prior Authorization Guideline

Guideline Name	HyQvia (immune globulin with recombinant human hyaluronidase)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: HyQvia (immune globulin with recombinant human hyaluronidase) for subcutaneous administration

Primary Immunodeficiency Indicated for the treatment of Primary Immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies. Limitation of Use: Safety and efficacy of chronic use of recombinant human hyaluronidase in HyQvia have not been established in conditions other than PI.

2 . Criteria

Product Name: HyQvia	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For patients with a primary immunodeficiency syndrome

AND

2 - Patient is 2 years of age or older

AND

3 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [2]

3.1 Documented failure to produce antibodies to specific antigens

OR

3.2 History of significant recurrent infections

3 . References

1. HyQvia Prescribing Information. Baxalta US Inc. Lexington, MA. April 2023.
2. Bonilla FA, Bernstein L, Khan DA, et. al. Practice management for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol. 2005;94(suppl):S1-S63.

Ibrance (palbociclib)

Prior Authorization Guideline

Guideline Name	Ibrance (palbociclib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Ibrance (palbociclib)
Breast Cancer Indicated for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: (1) an aromatase inhibitor as initial endocrine based therapy, or (2) fulvestrant in patients with disease progression following endocrine therapy.

2 . Criteria

Product Name: Ibrance	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of breast cancer

AND

2 - Prescribed by or in consultation with an oncologist

Product Name: Ibrance

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ibrance Prescribing Information. Pfizer Inc. New York, NY. December 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf Accessed April 15, 2022.

Prior Authorization Guideline

Guideline Name	IBS - Diarrhea
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Lotronex (alosetron hydrochloride)
<p>Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women Indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: • frequent and severe abdominal pain/discomfort • frequent bowel urgency or fecal incontinence • disability or restriction of daily activities due to IBS. Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.</p>
Drug Name: Viberzi (eluxadoline)
<p>Irritable bowel syndrome with diarrhea (IBS-D) Indicated in adults for the treatment of IBS-D.</p>

2 . Criteria

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms for at least 6 months [A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is female</p> <p style="text-align: center;">AND</p> <p>4 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure, contraindication, or intolerance to both of the following:</p> <ul style="list-style-type: none"> • antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6, B] • antidiarrheal agent [eg, loperamide] [2, 3, 6] 	

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Symptoms of IBS continue to persist

AND

2 - Documentation of positive clinical response to therapy as evidenced by one of the following: [1]

- Relief of IBS abdominal pain and discomfort
- Improvement in stool consistency
- Decrease in daily stool frequency
- Moderate or substantial improvement as measured by the Global Improvement Scale [C]

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of irritable bowel syndrome with diarrhea	
AND	
2 - Trial and failure, contraindication, or intolerance to both of the following:	
<ul style="list-style-type: none">• antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6]• antidiarrheal agent [eg, Lomotil (diphenoxylate and atropine)] [2, 3, 6]	

Product Name: Viberzi	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>2 - Symptoms of IBS continue to persist</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of positive clinical response to therapy as evidenced by both of the following: [D]</p> <ul style="list-style-type: none"> • Improvement in the daily worst abdominal pain score • Reduction in the Bristol Stool Scale 	

3 . Endnotes

- A. Lotronex was removed from the market in late 2000 due to reports of ischemic colitis and severe constipation but has since been re-released with a “black box” warning for use in select cases. [1, 3, 4, 5]
- B. Lotronex should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility. [1]
- C. The Global Improvement Scale (GIS) assesses multiple symptoms of Irritable Bowel Syndrome (IBS) using a 7-point Likert scale which ranges from symptoms substantially worse to substantially improved. GIS responders were defined as having moderate or substantial improvement in IBS symptoms. [1]
- D. The primary endpoint in Studies 1 and 2 to assess the efficacy of Viberzi was defined by both the simultaneous improvement in the daily worse abdominal pain score by $\geq 30\%$ as compared to the baseline weekly average AND a reduction in the BSS to < 5 on at least 50% of the days within a 12-week time interval. [7]

4 . References

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3. Wilkins T, Pepitone C, Alex B, Schade RR. Diagnosis and management of IBS in adults. *Am Fam Physician*. 2012;86(5):419-26.
4. Camiller M, Mayer EA, Drossman DA, et al. Improvement in the pain and bowel function in female irritable bowel patients with alosetron, a 5-HT₃ antagonist. *Aliment Pharmacol Ther* 1999;13(9):1149-5.
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7. Viberzi Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2020.
8. Alosetron Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. January 2016
9. Ford AC, Moayyedi P, Chey WD, Harris LA, Lacy BE, Saito YA, Quigley EMM; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2018 Jun;113(Suppl 2):1-18.

Prior Authorization Guideline

Guideline Name	Ibsrela (tenapanor) - PA, NF
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Ibsrela (tenapanor)
Irritable Bowel Syndrome with Constipation Indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

2 . Criteria

Product Name: Ibsrela	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of irritable bowel syndrome with constipation (IBS-C)	

AND

2 - Used as an adjunct to lifestyle modifications (e.g., increase intake of fibers and fluids, increase physical activity)

AND

3 - Trial and failure, contraindication, or intolerance to ONE the following:

- generic lactulose
- generic polyethylene glycol

AND

4 - Trial and failure, contraindication, or intolerance to Linzess

Product Name: Ibsrela	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following:	
<ul style="list-style-type: none">• Improvement in constipation or stool frequency from baseline• Decrease in abdominal pain or discomfort	

Product Name: Ibsrela	
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of irritable bowel syndrome with constipation (IBS-C)

AND

2 - Used as an adjunct to lifestyle modifications (e.g., increase intake of fibers and fluids, increase physical activity)

AND

3 - Submission of medical records (e.g. chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to ONE the following:

- generic lactulose
- generic polyethylene glycol

AND

4 - Submission of medical records (e.g. chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to Linzess

3 . References

1. Ibsrela prescribing information. Ardelyx, Inc. Waltham, MA. May 2021.
2. UpToDate. Wald, A. Treatment of Irritable Bowel Syndrome in Adults. Available at https://www.uptodate.com/contents/treatment-of-irritable-bowel-syndrome-in-adults?search=irritable%20bowe%20syndrome%20with%20constipation&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#H23037175. Accessed April 3, 2022.
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Iclusig (ponatinib)

Prior Authorization Guideline

Guideline Name	Iclusig (ponatinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Iclusig (ponatinib)
Chronic Myeloid Leukemia (CML) Indicated for the treatment of adult patients with chronic phase (CP) chronic myeloid leukemia (CML) with resistance or intolerance to at least two prior kinase inhibitors.
Accelerated phase (AP) or blast phase (BP) Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) Indicated for the treatment of adult patients with Accelerated phase (AP) or blast phase (BP) Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) for whom no other kinase inhibitors are indicated.
T315I-positive Chronic Myeloid Leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) Indicated for the treatment of adult patients with T315I-positive CML (chronic phase, accelerated phase, or blast phase) or T315I-positive Ph+ ALL.

2 . Criteria

Product Name: Iclusig

Diagnosis	Chronic Myelogenous Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic myelogenous leukemia</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist or oncologist</p>	

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Iclusig	
Diagnosis	Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia</p>	

AND

2 - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Iclusig	
Diagnosis	Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Iclusig Prescribing Information. ARIAD Pharmaceuticals, Inc. Cambridge, MA. August 2021.

Idhifa (enasidenib)

Prior Authorization Guideline

Guideline Name	Idhifa (enasidenib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Idhifa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of acute myeloid leukemia (AML) [2] AND 2 - Disease is one of the following: <ul style="list-style-type: none">• Relapsed	

- Refractory

AND

3 - Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH2 assay) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Idhifa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Idhifa therapy	

2 . References

1. Idhifa Prescribing Information. Celgene Corporation. Summit, NJ. August 2017.
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. v.2.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 9, 2017.

Igalmi (dexmedetomidine)

Prior Authorization Guideline

Guideline Name	Igalmi (dexmedetomidine)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Igalmi (dexmedetomidine)
Agitation Indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. Limitations of Use: The safety and effectiveness of Igalmi has not been established beyond 24 hours from the first dose.

2 . Criteria

Product Name: Igalmi	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following diagnoses:	

- Schizophrenia
- Bipolar I or II disorder

AND

2 - For the treatment of acute agitation [B, 1]

AND

3 - Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone) [C, 2-5]

AND

4 - Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid)

3 . Endnotes

- A. The safety and effectiveness of Igalmi has not been established beyond 24 hours from the 1st dose. Clinical studies were done on patients who were admitted to a clinical research unit or a hospital and remained under medical supervision for at least 24 hours following treatment. If agitation persists after the initial dose, up to two additional doses may be administered at least two hours apart. [13]
- B. We consider agitation to be a psychiatric emergency. Agitation is a state of motor restlessness or excitement and is often accompanied by mental tension and irritability. [14]
- C. With the emergence of second generation (atypical) antipsychotics(SGA's), the expert consensus-based guidelines recommend SGA's as 1st line therapy [2]

4 . References

1. Wilson, M., Pepper, D. et al. The Psychopharmacology of Agitation: Consensus Statement of the American Association for Emergency Psychiatry Project BETA Psychopharmacology Workgroup. West J Emerg Med. 2012 Feb; 13(1): 26–34. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3298219/>. Accessed June 6, 2022.

2. Garriga M, Pacchiarotti I, Kasper S, Zeller SL, Allen MH, Vazquez G, et al. Assessment and management of agitation in psychiatry: expert consensus. *World J Biol Psychiatry*. (2016) 17:86–128. doi: 10.3109/15622975.2015.1132007. Accessed June 6, 2022.
3. Zeller, S., Citrome, L. Managing Agitation Associated with Schizophrenia and Bipolar Disorder in the Emergency Setting. *West J Emerg Med*. 2016 Mar; 17(2): 165–172. doi: 10.5811/westjem.2015.12.28763. accessed June 6, 2022.
4. Miller, J. Managing acute agitation and aggression in the world of drug shortages. *Mental Health Clinician* (2021) 11 (6): 334–346. <https://doi.org/10.9740/mhc.2021.11.334>. Accessed June 6, 2022.
5. Schleifer, J. Management of acute agitation in psychosis: an evidence-based approach in the USA. Jan 2, 2018. Available at <https://www.cambridge.org/core/journals/advances-in-psychiatric-treatment/article/management-of-acute-agitation-in-psychosis-an-evidencebased-approach-in-the-usa/AC36BE73F3238B40EBDFC719B62D93E6>. Accessed June 6, 2022.
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8. Risperdal Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. March 2022..
9. Geodon Prescribing Information. Pfizer Inc. New York, NY. February 2022.
10. Abilify Prescribing Information. Otsuka America Pharmaceutical, Inc. Rockville, MD. August 2021.
11. Seroquel Prescribing Information. AstraZeneca Pharmaceuticals, LP. Wilmington, DE. January 2022.
12. Saphris Prescribing Information. Breckenridge Pharmaceuticals, Inc. Berlin, CT. July 2021.
13. Igalmi Prescribing Information. BioXcel Therapeutics, Inc. New Haven, CT. April 2022.
14. Marder, S. Uptodate. Psychosis in adults: Initial management. Available at https://www.uptodate.com/contents/psychosis-in-adults-initial-management?sectionName=INITIAL%20MANAGEMENT&search=AGITATION%20IN%20SCHIZOPHRENIA&topicRef=14805&anchor=H4035521878&source=see_link#H4035521878. Accessed June 6, 2022.

Prior Authorization Guideline

Guideline Name	Ilaris (canakinumab injection)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Ilaris (canakinumab injection)
<p>Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever(FMF) Indicated for the treatment of the following autoinflammatory Periodic Fever Syndromes: Cryopyrin-Associated Periodic Syndromes (CAPS), in adults and children 4 years of age and older including, Familial Cold Autoinflammatory Syndrome (FCAS) or Muckle-Wells Syndrome (MWS); Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients; Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients; Familial Mediterranean Fever (FMF) in adult and pediatric patients.</p> <p>Systemic Juvenile Idiopathic Arthritis (SJIA) Indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older.</p> <p>Still's disease (Adult-Onset Still's Disease [AOSD]) Indicated for the treatment of active Still's disease, including Adult-Onset Still's Disease (AOSD) in patients aged 2 years and older.</p>

2 . Criteria

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndromes [Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency(MKD), Familial Mediterranean Fever(FMF)]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following periodic fever syndromes:</p> <ul style="list-style-type: none"> • cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) • tumor necrosis factor (TNF) receptor associated periodic syndrome (TRAPS) • hyperimmunoglobulin D (Hyper-IgD) syndrome (HIDS/mevalonate kinase deficiency (MKD)) • familial mediterranean fever (FMF) <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Immunologist • Allergist • Dermatologist • Rheumatologist • Neurologist <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <ul style="list-style-type: none"> • Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab]) 	

- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <ul style="list-style-type: none"> • Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab]) • Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra]) 	

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active systemic juvenile idiopathic arthritis (SJIA)</p>	

AND

2 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [1, 2]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

AND

3 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline	

- Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline

AND

2 - Both of the following:

- Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab])
- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Still's Disease, including Adult-Onset Still's Disease (AOSD)</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to one of the following: [1-3]</p> <ul style="list-style-type: none"> • Corticosteroids (e.g., prednisone) • Methotrexate • Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <ul style="list-style-type: none"> • Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab]) 	

- Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra])

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Ilaris	
Diagnosis	Still's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <ul style="list-style-type: none"> • Patient is not receiving concomitant treatment with Tumor Necrosis Factor (TNF) inhibitors (e.g., Enbrel [etanercept], Humira [adalimumab], Remicade [infliximab]) • Patient is not receiving concomitant treatment with Interleukin-1 inhibitor (e.g., Arcalyst [rilonacept], Kineret [anakinra]) 	

3 . Definitions

Definition	Description
Cryopyrin-Associated Periodic Syndromes (CAPS):	A group of rare, autosomal dominantly inherited auto-inflammatory conditions comprising of Familial-Cold Auto-inflammatory Syndrome (FCAS), Muckle-Wells Syndrome (MWS), Neonatal-Onset Multisystem Inflammatory Disease (NOMID) or also known as Chronic Infantile Neurologic Cutaneous Articular Syndrome

	(CINCA), which are caused by the CIAS1 gene mutation and characterized by recurrent symptoms (urticaria-like skin lesions, fever chills, arthralgia, profuse sweating, sensorineural hearing/vision loss, and increased inflammation markers the blood). Approximately 300 people in the United States are affected by CAPS. [1, 4, 5]
Familial Cold Autoinflammatory Syndrome (FCAS):	The mildest form of CAPS, is characterized by cold-induced, daylong episodes of fever associated with rash, arthralgia, headaches and less frequently conjunctivitis, but without other signs of CNS inflammation. Symptoms usually begin during the first 6 months of life and are predominantly triggered by cold exposure. Duration of episodes usually is less than 24 hours. [5]
Muckle-Wells Syndrome (MWS):	A subtype of CAPS, which is characterized by episodic attacks of inflammation associated with a generalized urticaria-like rash, fever, malaise, arthralgia, and progressive hearing loss. Duration of symptoms usually lasts from 24-48 hours. [5]

4 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. September 2020.
2. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.
3. Mimura T, Kondo Y, Ohta A et al. Evidence-based clinical practice guideline for adult Still’s disease. *Mod Rheumatol.* 2018;28(5):736-757.
4. Lachmann HJ, Kone-Paut I, Kuemmerle-Deschner JB, et al. Use of canakinumab in the cryopyrin-associated periodic syndrome. *N Engl J Med.* 2009;360(23):2416-25.
5. Aksentijevich I, Putnam CD, Remmers EF, et al. Clinical continuum of cryopyrinopathies: novel CIAS1 mutations in North-American patients and a new cryopyrin model. *Arthritis Rheum.* 2007;56(4):1273-85.

Ilumya (tildrakizumab-asmn)

Prior Authorization Guideline

Guideline Name	Ilumya (tildrakizumab-asmn)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Ilumya (tildrakizumab-asmn)
Plaque Psoriasis Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

2 . Criteria

Product Name: Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Skyrizi (risankizumab)
- Stelara (ustekinumab)

- Tremfya (guselkumab)

AND

5.1.2 Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

5.2 For continuation of prior Ilumya therapy, defined as no more than a 45-day gap in therapy

Product Name: Ilumya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction the body surface area (BSA) involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline 	

3 . References

1. Ilumya prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. July 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Prior Authorization Guideline

Guideline Name	Imbruvica (ibrutinib)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Imbruvica (ibrutinib)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)
Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with 17p deletion Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL)/small lymphocytic leukemia (SLL) with 17p deletion
Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma Indicated for the treatment of adult patients with Waldenström's macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma [2]
Chronic graft versus host disease (cGVHD) Indicated for the treatment of adult and pediatric patients age 1 year and older with chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

2 . Criteria

Product Name: Imbruvica	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • chronic lymphocytic leukemia • small lymphocytic lymphoma 	

Product Name: Imbruvica	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Imbruvica	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Waldenstrom's Macroglobulinemia</p>	

Product Name: Imbruvica	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Imbruvica, Imbruvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic graft versus host disease (cGVHD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)</p>	

Product Name: Imbruvica, Imbruvica oral suspension	
Diagnosis	Chronic graft versus host disease (cGVHD)

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • chronic lymphocytic leukemia • small lymphocytic lymphoma <p style="text-align: center;">AND</p> <p>2 - Trial and failure, or intolerance to Imbruvica 140mg capsule</p>	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Notes

If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet

Diagnosis

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Approval Length

12 month(s)

Guideline Type

Non Formulary

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Notes

If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet

Diagnosis

Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma

Approval Length

6 month(s)

Therapy Stage

Initial Authorization

Guideline Type

Prior Authorization

Approval Criteria	
1 - Diagnosis of Waldenstrom's Macroglobulinemia	
AND	
2 - Trial and failure, or intolerance to Imbruvica 140mg capsule	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	
AND	
2 - Trial and failure, or intolerance to Imbruvica 140mg capsule	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of Waldenstrom's Macroglobulinemia	

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Notes

If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet

Diagnosis Chronic graft versus host disease (cGVHD)

Approval Length 6 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of chronic graft versus host disease (cGVHD)

AND

2 - Patient is 1 year of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)

AND

4 - Trial and failure, or intolerance to Imbruvica 140mg capsule

Notes

If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet

Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, or intolerance to Imbruvica 140mg capsule</p>	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Imbruvica 140mg tablet, Imbruvica 280mg tablet	
Diagnosis	Chronic graft versus host disease (cGVHD)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic graft versus host disease (cGVHD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate)</p>	

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Imbruvica 140mg capsule

Notes

If patient meets criteria above, please approve at GPI-14

3 . References

1. Imbruvica Prescribing Information. Pharmacyclics, Inc. Sunnyvale, CA. August 2022.
2. National Comprehensive Cancer Network Practice Guidelines in Oncology. Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma. V1.2017. NCCN Web site. http://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed March 18, 2020.

Prior Authorization Guideline

Guideline Name	Imcivree (setmelanotide) – PA, NF
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Imcivree (setmelanotide)
<p>Obesity Indicated for chronic weight management in adult and pediatric patients 6 years of age and older with obesity due to: 1) Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency confirmed by genetic testing demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS) 2) Bardet-Biedl Syndrome (BBS)</p> <p>Limitations of Use Imcivree is not indicated for the treatment of patients with the following conditions as Imcivree would not be expected to be effective: • Obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign • Other types of obesity not related to POMC, PCSK1 or LEPR deficiency, including obesity associated with other genetic syndromes and general (polygenic) obesity</p>

2 . Criteria

Product Name: Imcivree

Diagnosis	POMC, PCSK1, LEPR Deficiency
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 6 years of age or older</p> <p style="text-align: center;">AND</p> <p>2 - Patient has been diagnosed with obesity defined by one of the following:</p> <ul style="list-style-type: none"> • BMI greater than or equal to 30 kg/m² for adults 18 years of age or older • Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients <p style="text-align: center;">AND</p> <p>3 - Diagnosis is due to one of the following genetic deficiencies:</p> <ul style="list-style-type: none"> • Proopiomelanocortin (POMC) • Proprotein convertase subtilisin/kexin type 1 (PCSK1) • Leptin receptor (LEPR) <p style="text-align: center;">AND</p> <p>4 - Other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity)</p>	

Product Name: Imcivree	
Diagnosis	POMC, PCSK1, LEPR Deficiency
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is 6 years of age or older

AND

2 - Submission of medical records (e.g., chart notes) confirming diagnosis of obesity as defined by one of the following:

- BMI greater than or equal to 30 kg/m² for adults 18 years of age or older
- Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients

AND

3 - Submission of medical records (e.g., chart notes) confirming diagnosis is due to one of the following genetic deficiencies:

- Proopiomelanocortin (POMC)
- Proprotein convertase subtilisin/kexin type 1 (PCSK1)
- Leptin receptor (LEPR)

AND

4 - Submission of medical records (e.g., chart notes) confirming other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity)

Product Name: Imcivree	
Diagnosis	POMC, PCSK1, LEPR Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [A]

1.1.1 Patient has been on therapy for less than 12 months

AND

1.1.2 Weight loss of greater than or equal to 5% of baseline body weight

OR

1.2 Both of the following:

1.2.1 Patient has been on therapy for 12 months or more

AND

1.2.2 Weight loss of greater than or equal to 10% of baseline body weight

Product Name: Imcivree	
Diagnosis	POMC, PCSK1, LEPR Deficiency
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Submission of medical records (e.g., chart notes) confirming one of the following:	
1.1 Both of the following: [A]	

1.1.1 Patient has been on therapy for less than 12 months

AND

1.1.2 Weight loss of greater than or equal to 5% of baseline body weight

OR

1.2 Both of the following:

1.2.1 Patient has been on therapy for 12 months or more

AND

1.2.2 Weight loss of greater than or equal to 10% of baseline body weight

Product Name: Incivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient is 6 years of age or older	
AND	
2 - Patient has been diagnosed with obesity defined by one of the following:	
<ul style="list-style-type: none">• BMI greater than or equal to 30 kg/m² for adults 18 years of age or older• Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients	

AND

3 - Diagnosis of Bardet-Biedl syndrome (BBS)

AND

4 - Other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity)

Product Name: Imcivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Patient is 6 years of age or older	
AND	
2 - Submission of medical records (e.g., chart notes) confirming diagnosis of obesity as defined by one of the following:	
<ul style="list-style-type: none">• BMI greater than or equal to 30 kg/m² for adults 18 years of age or older• Weight greater than or equal to 95th percentile using growth chart assessments for pediatric patients	
AND	
3 - Diagnosis of Bardet-Biedl syndrome (BBS)	

AND

4 - Submission of medical records (e.g., chart notes) confirming other causes or types of obesity have been ruled out (e.g., obesity due to suspected POMC, PCSK1, or LEPR deficiency with POMC, PCSK1, or LEPR variants classified as benign or likely benign; obesity associated with other genetic syndromes; polygenic obesity)

Product Name: Imcivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Both of the following: [B]	
1.1 Patient has been on therapy for 12 months or more	
AND	
1.2 Weight loss of greater than or equal to 5% of baseline body weight	

Product Name: Imcivree	
Diagnosis	Bardet-Biedl syndrome (BBS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
Approval Criteria	
1 - Submission of medical records (e.g., chart notes) confirming both of the following: [B]	

1.1 Patient has been on therapy for 12 months or more

AND

1.2 Weight loss of greater than or equal to 5% of baseline body weight

3 . Endnotes

- A. For obesity due to POMC, PCSK1, or LEPR deficiency, patient should be evaluated for response to Imcivree after 12-16 weeks of treatment. If a patient has not lost at least 5% of baseline body weight or 5% of baseline BMI, it is recommended to discontinue Imcivree as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment. [1]
- B. For obesity due to BBS, patient should be evaluated for response to Imcivree after one year of treatment. If a patient has not lost at least 5% of baseline body weight or 5% of baseline BMI for patients aged less than 18 years, discontinue Imcivree as it is unlikely that the patient will achieve and sustain clinically meaningful weight loss with continued treatment. [1]

4 . References

1. Imcivree Prescribing Information. Rhythm Pharmaceuticals, Inc. Boston, MA. June 2022.
2. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: <https://www.micromedexsolutions.com/>. Accessed January 8, 2021.
3. Perreault, M. Genetic contribution and pathophysiology of obesity. UpToDate. www.uptodate.com. Updated November 22, 2019. Accessed January 8, 2021.
4. Barlow SE and the Expert Committee. Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report. *Pediatrics* 2007;120 Supplement December 2007:S164—S192.

Prior Authorization Guideline

Guideline Name	Immune Globulins - PA, NF
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Bivigam and Octagam 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency disorders associated with defects in humoral immunity. These include, but are not limited to: congenital agammaglobulinemia, X-linked agammaglobulinemia, common variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.
Drug Name: Flebogamma 5% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated in adults and pediatric patients 2 years of age and older for the treatment of primary immunodeficiency (PI), including the humoral immune defects in common variable immunodeficiency, x-linked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.
Drug Name: Flebogamma 10% (immune globulin [Human])
Primary Immunodeficiency Disorders Indicated as replacement therapy in primary immunodeficiency (PI) including the humoral immune defects in common variable immunodeficiency, xlinked agammaglobulinemia, severe combined immunodeficiency, and Wiskott-Aldrich syndrome.

Chronic Primary Immune Thrombocytopenia (ITP) Indicated for the treatment of patients 2 years of age and older with chronic primary ITP to raise platelet count.

Drug Name: Gamastan (immune globulin [Human])

Measles (Rubeola) Indicated to prevent or modify measles in a susceptible person exposed fewer than 6 days previously. A susceptible person is one who has not been vaccinated and has not had measles previously. Gamastan may be especially indicated for susceptible household contacts of measles patients, particularly contacts under 1 year of age, for whom the risk of complications is highest. Gamastan is also indicated for pregnant women without evidence of immunity. Gamastan and measles vaccine should not be given at the same time. If a child is older than 12 months and has received Gamastan, he should be given measles vaccine about 5 months later when the measles antibody titer will have disappeared. If a susceptible child exposed to measles is immunocompromised, give Gamastan immediately.

Rubella Indicated to modify rubella in exposed women who will not consider a therapeutic abortion. Some studies suggest that the use of Gamastan in exposed, susceptible women can lessen the likelihood of infection and fetal damage; therefore, Gamastan may benefit those women who will not consider a therapeutic abortion. Do not give Gamastan for routine prophylaxis of rubella in early pregnancy to an unexposed woman.

Hepatitis A Indicated for prophylaxis following exposure to hepatitis A. The prophylactic value of Gamastan is greatest when given before or soon after exposure to hepatitis A. Gamastan is not indicated in persons with clinical manifestations of hepatitis A or in those exposed more than 2 weeks previously.

Varicella Indicated to modify varicella. Passive immunization against varicella in immunosuppressed patients is best accomplished by use of Varicella Zoster Immune globulin (Human) [VZIG]. If VZIG is unavailable, Gamastan, promptly given, may also modify varicella.

Drug Name: Carimune NF (immune globulin [Human])

Idiopathic Thrombocytopenic Purpura (ITP) (1) Acute ITP: A controlled study was performed in children in which Carimune was compared with steroids for the treatment of acute (defined as less than 6 months duration) ITP. In this study sequential platelet levels of 30,000, 100,000, and 150,000/microliter were all achieved faster with Carimune than with steroids and without any of the side effects associated with steroids. However, it should be noted that many cases of acute ITP in childhood resolve spontaneously within weeks to months. Carimune has been used with good results in the treatment of acute ITP in adult patients. In a study involving 10 adults with ITP of less than 16 weeks duration, Carimune therapy raised the platelet count to the normal range after a 5 day course. This effect lasted a mean of over 173 days, ranging from 30 to 372 days. (2) Chronic ITP: Children and adults with chronic (defined as greater than 6 months duration) ITP have also shown an increase (sometimes temporary) in platelet counts upon administration of Carimune. Therefore, in situations that require a rapid rise in platelet count, for example prior to surgery or to control excessive bleeding, use of Carimune should be considered. In children with chronic ITP, Carimune therapy resulted in a mean rise in platelet count of 312,000/microliter with a duration of increase ranging from 2 to 6 months. Carimune therapy may be considered as a means to defer or avoid splenectomy. In adults, Carimune therapy has been shown to be effective in maintaining the platelet count in an acceptable range with or without periodic

booster therapy. The mean rise in platelet count was 93,000/microliter and the average duration of the increase was 20-24 days. However, it should be noted that not all patients will respond. Even in those patients who do respond, this treatment should not be considered to be curative.

Primary Immunodeficiency Disorders Indicated for the maintenance treatment of patients with primary immunodeficiencies (PID), e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency. Carimune NF is preferable to intramuscular Immune Globulin (Human) preparations in treating patients who require an immediate and large increase in the intravascular immunoglobulin level, in patients with limited muscle mass, and in patients with bleeding tendencies for whom intramuscular injections are contraindicated. The infusions must be repeated at regular intervals.

Drug Name: Privigen (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of patients age 15 years and older with chronic ITP to raise platelet counts.

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI). This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment. Limitation of Use: Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Privigen in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.

Drug Name: Gammagard S/D (immune globulin [Human])

Kawasaki Disease Indicated for the prevention of coronary artery aneurysms associated with Kawasaki syndrome in pediatric patients.

B-cell Chronic Lymphocytic Leukemia (CLL) Indicated for prevention of bacterial infections in hypogammaglobulinemia and/or recurrent bacterial infections associated with B-cell Chronic Lymphocytic Leukemia (CLL).

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adult chronic idiopathic thrombocytopenic purpura to increase platelet count and to prevent and/or to control bleeding.

Primary Immunodeficiency Disorders Indicated for the treatment of primary immunodeficiency (PI) associated with defects in humoral immunity, in adults and children two years and older. This includes, but is not limited to, congenital agammaglobulinemia, common

variable immunodeficiency, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Gammaked and Gamunex-C (immune globulin [Human])

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of CIDP in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse.

Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults and children with idiopathic thrombocytopenic purpura to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Immune globulin products (IVIG)

Off Label Uses: Bone Marrow Transplant (BMT) [6, 21-24] Has been used to decrease the incidence of infections and graft versus host disease (GVHD) in patients 20 years of age and older who underwent bone marrow transplantation.

Dermatomyositis [6, 25-29] In patients with treatment-resistant dermatomyositis, IVIG therapy resulted in improvements in muscle strength and neuromuscular symptoms.

Multifocal Motor Neuropathy (MMN) [6, 30, 34] In placebo-controlled trials, IVIG has been shown to improve strength and reduce disability and conduction block in patients with MMN.

Pediatric HIV [6, 35-37, 75] Used to decrease the frequency of serious and minor bacterial infections; the frequency of hospitalization; and to increase the time free of serious bacterial infections in patients with HIV.

Guillain-Barre Syndrome [6, 38-40] Considered to be equally effective as plasma exchange for the treatment of Guillain-Barre Syndrome.

Lambert-Eaton Myasthenic Syndrome [6, 41] Shown to produce short-term improvement in strength in patients with Lambert-Eaton Myasthenic Syndrome.

Myasthenia Gravis [6, 72, 74] A clinical study comparing IVIG with plasma exchange did not show a significant difference between the two treatments in patients with myasthenia gravis exacerbation. Several open studies support beneficial effects of IVIG in treating myasthenia gravis.

Relapsing Remitting Multiple Sclerosis [6, 50, 52] Published studies indicate that IVIG may reduce the frequency of acute exacerbations and provide symptomatic relief in patients with relapsing-remitting forms of multiple sclerosis.

Stiff-Person Syndrome [6, 83, 84] The efficacy of IVIG for the treatment of stiff-person

syndrome was demonstrated in a randomized, double-blind, placebo-controlled, crossover trial.

Polymyositis [6, 64] Found to be effective in reversing chronic polymyositis previously unresponsive to immunosuppressive therapy.

Drug Name: Gammagard liquid (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age or older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Multifocal Motor Neuropathy (MMN) Indicated as a maintenance therapy to improve muscle strength and disability in adult patients with Multifocal Motor Neuropathy (MMN).

Drug Name: Gammaplex (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated for replacement therapy in primary humoral immunodeficiency (PI) in adults and pediatric patients two years of age and older. This includes, but is not limited to, the humoral immune defect in common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenic Purpura (ITP) Indicated for the treatment of adults with chronic immune thrombocytopenic purpura (ITP) to raise platelet counts.

Drug Name: Octagam 10% (immune globulin [Human])

Chronic Immune Thrombocytopenic Purpura Indicated in chronic immune thrombocytopenic purpura to rapidly raise platelet counts to control or prevent bleeding in adults.

Dermatomyositis Indicated for the treatment of dermatomyositis in adults.

Drug Name: Cytogam (human cytomegalovirus immune globulin liquid)

Cytomegalovirus Indicated for the prophylaxis of cytomegalovirus disease associated with transplantation of kidney, lung, liver, pancreas and heart. In transplants of these organs other than kidney from CMV seropositive donors into seronegative recipients, prophylactic CMV-IGIV should be considered in combination with ganciclovir.

Drug Name: Varizig (varicella zoster immune globulin [Human] solution)

Post-exposure prophylaxis of varicella Indicated for post-exposure prophylaxis of varicella in high risk individuals. High risk groups include: immunocompromised children and adults, newborns of mothers with varicella shortly before or after delivery, premature infants, neonates and infants less than one year of age, adults without evidence of immunity,

pregnant women. Limitations of Use: There is no convincing evidence that Varizig reduces the incidence of chickenpox infection after exposure to VZV. There is no convincing evidence that established infections with VZV can be modified by Varizig administration. There is no indication for the prophylactic use of Varizig in immunodeficient children or adults when there is a past history of varicella, unless the patient is undergoing bone marrow transplantation.

Drug Name: Hizentra (immune globulin [Human] liquid)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment. Limitations of Use: Hizentra maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Maintenance therapy beyond these periods should be individualized based upon the patient's response and need for continued therapy.

Drug Name: Panzyga (immune globulin intravenous [Human] - ifas)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Chronic Immune Thrombocytopenia (ITP) Indicated for the treatment of adult patients with ITP to raise platelet counts to control or prevent bleeding.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Indicated for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.

Drug Name: Cuvitru (immune globulin [Human])

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adult and pediatric patients two years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Cutaquig (Immune globulin subcutaneous [Human] - hipp)

Primary Immunodeficiency Disorders Indicated as replacement therapy for primary humoral immunodeficiency (PI) in adults and pediatric patients 2 years of age and older. This includes, but is not limited to, common variable immunodeficiency (CVID), X-linked

agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Xembify (immune globulin subcutaneous, human - klhw)

Primary Immunodeficiency Disorders Indicated for treatment of primary humoral immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Drug Name: Asceniv (immune globulin intravenous, human - slra)

Primary Immunodeficiency Disorders Indicated for the treatment of primary humoral immunodeficiency (PI) in adults and adolescents (12 to 17 years of age). PI includes, but is not limited to, the humoral immune defect in congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies (SCID).

2 . Criteria

Product Name: Intravenous or subcutaneous immune globulins (IVIG or SCIG)

Diagnosis	Primary Immunodeficiency Syndrome
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Approval Length	12 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]

AND

2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

Product Name: Asceniv, Cutaquig, Panzyga	
Diagnosis	Primary Immunodeficiency Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - For patients with a primary immunodeficiency syndrome [1, 3, 5, 6, 57, 61, 65-71, I, J]	
AND	
2 - Clinically significant functional deficiency of humoral immunity as evidenced by one of the following: [73]	

2.1 Documented failure to produce antibodies to specific antigens

OR

2.2 History of significant recurrent infections

AND

3 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following (applies to Cutaquig only):

- Cuvitru
- Hizentra
- Xembify

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]	

AND

2 - Documented platelet count of less than $50 \times 10^9 / L$ [85]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga

Diagnosis	Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of idiopathic thrombocytopenic purpura (ITP) [3, 5, 62, 68-70, 88]

AND

2 - Documented platelet count of less than $50 \times 10^9 / L$ [85]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard

- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulins (IVIG)	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Kawasaki Disease [5]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Asceniv, Panzyga	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Kawasaki Disease [5]</p>	

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulins (IVIG)

Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
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Approval Length	12 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga

Diagnosis	B-cell Chronic Lymphocytic Leukemia (CLL) [5, 10-14]
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of B-cell chronic lymphocytic leukemia (CLL) [5]

AND

2 - One of the following:

2.1 Documented hypogammaglobulinemia (IgG less than 500 mg/dL) [13, 14, 78, B]

OR

2.2 History of bacterial infection(s) associated with B-cell CLL [13-15, 78, A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:</p> <p>1.1 Progressive symptoms present for at least 2 months</p> <p style="text-align: center;">AND</p> <p>1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:</p> <p>1.2.1 Progressive or relapsing motor impairment of more than one limb</p> <p style="text-align: center;">OR</p> <p>1.2.2 Progressive or relapsing sensory impairment of more than one limb</p> <p style="text-align: center;">AND</p> <p>1.3 Electrophysiologic findings when three of the following four criteria are present:</p> <ul style="list-style-type: none"> • Partial conduction block of 1 or more motor nerve • Reduced conduction velocity of 2 or more motor nerves • Prolonged distal latency of 2 or more motor nerves • Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves <p style="text-align: center;">AND</p>	

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG), Hizentra	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as measured by an objective scale (e.g., Rankin, Modified Rankin, Medical Research Council [MRC] scale) [77, H, P]</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [P]</p>	

Product Name: Asceniv, Panzyga	
Diagnosis	Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) [15-20, 55, 58, 62, C, H]
Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p>	

1 - Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) as confirmed by all of the following [77, C]:

1.1 Progressive symptoms present for at least 2 months

AND

1.2 Symptomatic polyradiculoneuropathy as indicated by one of the following:

1.2.1 Progressive or relapsing motor impairment of more than one limb

OR

1.2.2 Progressive or relapsing sensory impairment of more than one limb

AND

1.3 Electrophysiologic findings when three of the following four criteria are present:

- Partial conduction block of 1 or more motor nerve
- Reduced conduction velocity of 2 or more motor nerves
- Prolonged distal latency of 2 or more motor nerves
- Prolonged F-wave latencies of 2 or more motor nerves or the absence of F waves

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Gamastan	
Diagnosis	Hepatitis A

Approval Length	14 Day(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For prophylaxis of Hepatitis A before or soon after exposure [57, 93]</p> <p style="text-align: center;">AND</p> <p>2 - Patient does not have clinical manifestations of hepatitis A [57, 93]</p> <p style="text-align: center;">AND</p> <p>3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [57, 93]</p>	

Product Name: Gamastan	
Diagnosis	Measles (Rubeola)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [57, 93]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is not receiving measles vaccine at the same time [57, 93]</p>	

Product Name: Gamastan	
Diagnosis	Varicella
Approval Length	14 Day(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For passive immunization against varicella [57, 93]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is immunosuppressed [57, 93]</p> <p style="text-align: center;">AND</p> <p>3 - Varicella Zoster Immune Globulin (Human) vaccine is not available</p>	

Product Name: Gamastan	
Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For pregnant women who are exposed or susceptible to Rubella [57, 93]</p> <p style="text-align: center;">AND</p> <p>2 - Patient will not consider a therapeutic abortion [57, 93]</p>	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]

AND

2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Bone Marrow Transplantation (off-label) [21-24]
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Confirmed allogeneic bone marrow transplant within the last 100 days [21-23, D]	
AND	
2 - Documented severe hypogammaglobulinemia (IgG less than 400 mg/dL) [21, D]	
AND	

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of HIV disease [35, 75, K]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is less than or equal to 13 years of age [75, 80]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]</p> <p style="text-align: center;">OR</p> <p>3.2 Functional antibody deficiency as demonstrated by one of the following: [79]</p> <ul style="list-style-type: none">• Poor specific antibody titers• Recurrent bacterial infections	

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga

Diagnosis	HIV (off-label) [35-37, 75, 79, 80]
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of HIV disease [35, 75, K]

AND

2 - Patient is less than or equal to 13 years of age [75, 80]

AND

3 - One of the following:

3.1 Documented hypogammaglobulinemia (IgG less than 400 mg/dL) [75, L]

OR

3.2 Functional antibody deficiency as demonstrated by one of the following: [79]

- Poor specific antibody titers

- Recurrent bacterial infections

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:</p> <p>1.1 Weakness with slowly progressive or stepwise progressive course over at least one month</p> <p style="text-align: center;">AND</p> <p>1.2 Asymmetric involvement of two or more nerves</p> <p style="text-align: center;">AND</p> <p>1.3 Absence of both of the following:</p> <p>1.3.1 Motor neuron signs</p>	

AND

1.3.2 Bulbar signs

AND

2 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as measured by an objective scale [e.g., Rankin, Modified Rankin, Medical Research Council (MRC) scale] [76, 87]	
AND	
2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect	

Product Name: Asceniv, Panzyga	
Diagnosis	Multifocal Motor Neuropathy (off-label) [30-34]
Approval Length	12 month(s)

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:</p> <p>1.1 Weakness with slowly progressive or stepwise progressive course over at least one month</p> <p style="text-align: center;">AND</p> <p>1.2 Asymmetric involvement of two or more nerves</p> <p style="text-align: center;">AND</p> <p>1.3 Absence of both of the following:</p> <p>1.3.1 Motor neuron signs</p> <p style="text-align: center;">AND</p> <p>1.3.2 Bulbar signs</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Plegridy (peginterferon beta-1a)*
- Rebif (interferon beta-1a)*
- Tecfidera (dimethyl fumarate)*
- Tysabri (natalizumab)*

AND

4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammaplex
- Gamunex-C

<ul style="list-style-type: none"> • Privigen 	
Notes	*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 50, 52, 75, O]:</p> <p>1.1 Findings of interval examination including neurological deficits incurred</p> <p style="text-align: center;">AND</p> <p>1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composite [MSFC], Disease Steps [DS])</p> <p style="text-align: center;">AND</p> <p>2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 50, 52, 75]</p> <p style="text-align: center;">AND</p> <p>3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 50, 52, 75]</p> <p style="text-align: center;">AND</p> <p>4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)</p>	

AND

5 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga

Diagnosis	Relapsing-Remitting Multiple Sclerosis (off-label) [50-52]
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of relapsing remitting multiple sclerosis (RRMS)) [6, 50, 52, 75, G]

AND

2 - Documentation of an MS exacerbation or progression (worsening) of the patient's clinical status from the visit prior to the one prompting the decision to initiate immune globulin therapy [6, 50, 52, 75, G, M, O]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following agents: [52, G, M, O]

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Betaseron (interferon beta-1b)*
- Copaxone/Glatopa (glatiramer acetate)*
- Generic dimethyl fumarate
- Gilenya (Fingolimod)*
- Lemtrada (alemtuzumab)*
- Tysabri (natalizumab)*

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Notes

*This agent may require prior authorization.

Product Name: Intravenous immune globulin (IVIG)

Diagnosis Myasthenia Gravis Exacerbation (off-label) [45-49]

Approval Length 3 month(s)

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):

- Gammagard
- Gammalex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga

Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
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Approval Length	3 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of generalized myasthenia gravis [45, 72, 74, F, R]

AND

2 - Evidence of myasthenic exacerbation, defined by one of the following symptoms in the last month: [45, 72, 74, F, R]

2.1 Difficulty swallowing

OR

2.2 Acute respiratory failure

OR

2.3 Major functional disability responsible for the discontinuation of physical activity

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, mycophenolate mofetil, cyclosporine), unless contraindicated, will be used for long-term management of myasthenia gravis [45, 72, 74, F, R]

AND

4 - Prescribed by or in consultation with a neurologist

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of stiff-person syndrome [55, 83, 84]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga

Diagnosis | Stiff Person Syndrome (off-label) [53]

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses [29]:</p> <ul style="list-style-type: none"> • Dermatomyositis • Polymyositis <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga

Diagnosis	Dermatomyositis and Polymyositis (off-label) [6, 25-29, 64]
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Intravenous immune globulin (IVIG)

Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Guillain-Barre Syndrome</p> <p style="text-align: center;">AND</p> <p>2 - Patients with severe disease requiring aid to walk [40, E]</p> <p style="text-align: center;">AND</p> <p>3 - Onset of neuropathic symptoms within the last four weeks [40, E]</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Guillain-Barre Syndrome</p> <p style="text-align: center;">AND</p> <p>2 - Patients with severe disease requiring aid to walk [40, E]</p> <p style="text-align: center;">AND</p> <p>3 - Onset of neuropathic symptoms within the last four weeks [40, E]</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:</p> <ul style="list-style-type: none">• Gammagard• Gammaplex• Gamunex-C• Privigen	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]</p> <p style="text-align: center;">AND</p> <p>2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]</p> <p style="text-align: center;">AND</p> <p>3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to two of the following (applies to Asceniv and Panzyga only):</p> <ul style="list-style-type: none"> • Gammagard • Gammaplex • Gamunex-C • Privigen 	

Product Name: Intravenous immune globulin (IVIG)	
Diagnosis	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect

Product Name: Asceniv, Panzyga

Diagnosis | Lambert-Eaton Myasthenic Syndrome (off-label) [41]

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (e.g., azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two of the following:

- Gammagard
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Cytogam	
Diagnosis	Prophylaxis for CMV Infection
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation</p> <p style="text-align: center;">AND</p> <p>1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive</p> <p style="text-align: center;">AND</p> <p>1.2.3 Used in combination with ganciclovir or valganciclovir unless the patient has a hypersensitivity to, is intolerant of, or therapy is deemed inappropriate</p>	

Product Name: Varizig	
Diagnosis	Varicella

Approval Length	1 Dose
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For passive immunization or post exposure-prophylaxis of varicella</p> <p style="text-align: center;">AND</p> <p>2 - Patient is considered a high risk individual (e.g., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old)</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed immune globulin is being used intramuscularly</p>	

3 . Endnotes

- A. Guidelines from the British Committee for Standards in Haematology [11] and the National Comprehensive Cancer Network [16] state that IVIG therapy may be beneficial in patients with recurrent infections. Clinical studies show that IVIG reduces the number of bacterial infections, but not viral or fungal infections. [24]
- B. Based on inclusion criteria from Molica et al. [14]
- C. According to published data, there appears to be no difference in efficacy among IVIG, plasma exchange, and corticosteroids. [15, 17, 20]
- D. A controlled trial indicated that treatment with IVIG beyond three months was associated with a delayed recovery of humoral immunity, and the rate of infections after two years of treatment was increased significantly in IVIG recipients. [25] Centers for Disease Control and Prevention, Infectious Disease Society of America, and American Society of Blood and Marrow Transplantation guidelines recommended routine IVIG use to prevent bacterial infections among BMT recipients with unrelated marrow grafts who experience severe hypogammaglobulinemia (e.g., IgG < 400 mg/dl) within the first 100 days after transplant. [21]
- E. The American Academy of Neurology recommends that IVIG is for patients with GBS who require aid to walk within 2 weeks from the onset of neuropathic symptoms. [40]
- F. The effectiveness of IVIG for moderate-to-severe but stable myasthenia gravis, or for moderate exacerbations of myasthenia gravis have not been demonstrated in adequately controlled trials. [48] IVIG may be as effective as plasma exchange for patients with acute exacerbations of myasthenia gravis. [45] The indications for the use of IVIG are the same as those for plasma exchange: to produce rapid improvement to

help the patient through a difficult period of myasthenic weakness. It has the advantages of not requiring special equipment or large-bore vascular access. [59] The usual dose of immune globulin is 400 mg per kilogram per day for five successive days. The improvement rate after immune globulin treatment, calculated from eight published reports, was 73 percent, but this figure is likely to be biased by selective reporting of positive uncontrolled trials. In patients who respond, improvement begins within four to five days. The effect is temporary but may be sustained for weeks to months, allowing intermittent long-term therapy in patients with otherwise refractory disease.

- G. Guidelines from the American Academy of Neurology [42] state that interferon Beta or glatirimer are appropriate treatments for patients who have relapsing-remitting multiple sclerosis. The guidelines state that it is only possible that IVIG reduces the attack rate in RRMS, and that current evidence suggests IVIG is of little benefit with regard to slowing disease progression.
- H. Treatment for CIDP includes corticosteroids such as prednisone, which may be prescribed alone or in combination with immunosuppressant drugs. [58] Plasmapheresis and intravenous immunoglobulin (IVIG) therapy are effective. IVIG may be used even as a first-line therapy. Physiotherapy may improve muscle strength, function and mobility, and minimize the shrinkage of muscles and tendons and distortions of the joints.
- I. Subcutaneous formulations of immune globulin are available for the treatment of patients with primary immune deficiency. Subcutaneous infusions may be an alternative for patients with adverse effects to intravenous infusions of immune globulin or with poor venous access. Other advantages include decreased cost of administration, independence from scheduled home nursing visits, better maintenance of intravenous immune globulin trough levels, and a serum IgG profile (smaller variation in the peak and trough IgG concentrations compared to intravenous administration) that is similar to that in a normal population. Disadvantages include more frequent infusions and local reactions. [6]
- J. There are good data to show that all immune globulins (IVIG/SCIG) are effective for primary immunodeficiency. There are no data for SCIG for indications other than PI. Efficacy is a class effect for all immune globulins products. It is appropriate to combine all IVIG/SCIG products as they are used interchangeably for PI; can combine all IVIG for other indications. Gamastan S/D (IMIG) has unique indications and should be available on the formulary. [74]
- K. IVIG has been used in children with symptomatic human immunodeficiency virus (HIV) infection who are immunosuppressed in association with acquired immunodeficiency syndrome (AIDS) or AIDS-related complex (ARC) in an attempt to control or prevent infections and improve immunologic parameters. Results of studies in adults and children with symptomatic HIV infection indicate that IVIG, used in dosages similar to those used for replacement therapy in patients with primary immunodeficiencies, reduces the incidence of recurrent bacterial infections and sepsis, including upper respiratory tract infections. [75]
- L. The ACIP, American Academy of Pediatrics (AAP), Centers for Disease Control (CDC), National Institutes of Health (NIH), HIV Medicine Association of the Infectious Diseases Society of America (IDSA), Pediatric Infectious Diseases Society, and other experts state that HIV-infected infants and children who have hypogammaglobulinemia (IgG less than 400 mg/dL) should receive IVIG (400 mg/kg once every 2-4 weeks) to prevent serious bacterial infections. [75]
- M. Per expert consultant regarding MS: IVIG is only used in acute, severe MS. IVIG is used for bad relapses of MS with significant neurological dysfunction when a patient is breaking through their regular maintenance medications. It takes about 3 months to see

if there is improvement in MS and one cannot say a patient has failed a medication if they have a breakthrough episode of MS within this 3 month period [86].

- N. Per expert consultant regarding multifocal motor neuropathy: the European Federation of Neurological Societies (EFNS) guidelines [88] as outlined on page 344 and in the table are fairly reasonable: 1. Weakness with slowly progressive or stepwise progressive course 2. Asymmetric involvement of two or more nerves 3. Absence of upper motor neuron signs and bulbar signs [87].
- O. Per expert consultant regarding MS: there are no data to support the initial length of IVIG treatment in MS. I would suggest 3 months and then reevaluate. An appropriate length of time for reauthorization of IVIG is 12 months. Patients who receive IVIG for RRMS should be in acute exacerbation, should have tried steroids, have documentation of inability to tolerate other disease modifying drugs, as well as show progression of disease. IVIG should be used 2nd or 3rd line if other injectable disease modifying drugs are not tolerated. Guidelines do not support IVIG as first line treatment for MS [87].
- P. Per expert consultant regarding CIDP: It is important to reevaluate a patient after initial treatment. Some patients may need changes in dosing intervals due to wearing off of a dose within 2-3 weeks. Treatment can be lifelong for some patient [87].
- Q. Per expert consultant regarding dermatomyositis: It is reasonable to ask a patient to try steroids prior to treatment with IVIG. [87]
- R. Per expert consultant regarding MG: IVIG should be used in patients with moderate to severe myasthenia gravis with acute exacerbation. Most MDs favor plasma exchange for maintenance therapy in MG patients. Myasthenic exacerbation = myasthenic crisis. [87]

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Inbrija (levodopa) inhalation powder

Prior Authorization Guideline

Guideline Name	Inbrija (levodopa) inhalation powder
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Inbrija (levodopa inhalation powder)
Parkinson's disease Indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa.

2 . Criteria

Product Name: Inbrija	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Parkinson's disease	

AND

2 - Patient is experiencing intermittent OFF episodes

AND

3 - Patient is receiving Inbrija in combination with carbidopa/levodopa

AND

4 - Trial and failure, contraindication or intolerance to one of the following: [A]

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Inbrija	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to Inbrija therapy	
AND	
2 - Patient is receiving Inbrija in combination with carbidopa/levodopa	

3 . Endnotes

- A. Primary treatment options for patients experiencing intermittent OFF episodes depends on the severity of the episodes. The easiest options include: shortening the dosing interval of levodopa, advising patient to take levodopa on an empty stomach if possible, or crushing the tablet and ingesting it with carbonated water for more predictable and faster absorption. Following the trial of the above options, entacapone, MAO-B Inhibitors or Dopamine Agonists may be added to the patient's therapy to enhance dopamine levels. [2]

4 . References

1. Inbrija Prescribing Information. Acorda Therapeutics, Inc. Ardsley, NY. December 2018.
2. Per clinical consult with neurologist, March 27, 2019.

Increlex (mecasermin [rDNA origin])

Prior Authorization Guideline

Guideline Name	Increlex (mecasermin [rDNA origin])
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Increlex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following: [A]</p> <p>1.1 All of the following:</p> <p>1.1.1 Diagnosis of severe primary IGF-1 deficiency [3]</p> <p style="text-align: center;">AND</p>	

1.1.2 Height standard deviation score less than or equal to -3.0

AND

1.1.3 Basal IGF-1 standard deviation score less than or equal to -3.0

AND

1.1.4 Normal or elevated growth hormone

AND

1.1.5 Prescribed by or in consultation with a pediatric endocrinologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH

AND

1.2.2 Prescribed by or in consultation with a pediatric endocrinologist

Notes	NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. Increlex is not a substitute for GH for approved GH indications.
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Product Name: Increlex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Growth increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [2, B]

- Previous height and date obtained
- Current height and date obtained

AND

2 - Both of the following:

- Expected adult height is not obtained
- Documentation of expected adult height goal

Notes

NOTE: Increlex is not a substitute for GH for approved GH indications.

2 . Endnotes

- A. Growth Hormone Deficiency (GHD) and severe Primary IGF-1 Deficiency (IGFD) are two distinct hormone disorders. Patients with severe Primary IGFD are not GH deficient, and therefore, exogenous GH treatment cannot be expected to resolve the patient's growth deficiency. [1]
- B. Typically near-adult height is defined as bone age of 16 years or more for males and 14 years or more for females and a growth rate less than 2 cm/year for 1 year. [2]

3 . References

1. Increlex Prescribing Information. Ipsen Biopharmaceuticals, Inc. Basking RIdge, NJ. March 2016.
2. Mauras N, Attie KM, Reiter EO, Saenger P, Baptista J. High dose recombinant human growth hormone (GH) treatment of GH-deficient patients in puberty increases near-final height: a randomized, multicenter trial. Genentech, Inc., Cooperative Study Group. J Clin Endocrinol Metab. 2000;85(10):3653-60.
3. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. Horm Res Paediatr. 2016;86:361-397. Available at: <https://www.karger.com/Article/Pdf/452150>. Accessed July 6, 2018.

Prior Authorization Guideline

Guideline Name	Infliximab – PA, NF
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)

Crohn’s Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy. Also indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn’s disease.

Pediatric Crohn’s Disease Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn’s disease who have had an inadequate response to conventional therapy.

Ulcerative Colitis Indicated for reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Pediatric Ulcerative Colitis Indicated for reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.

Rheumatoid Arthritis Indicated in combination with methotrexate, for reducing signs and

symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis.

Ankylosing Spondylitis Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Psoriatic Arthritis Indicated for reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis.

Plaque Psoriasis Indicated for the treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. Therapy should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Off Label Uses: Sarcoidosis Has been used for the treatment of refractory sarcoidosis. [5-7]

2 . Criteria

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none"> • Moderately to severely active Crohn's disease [B] • Fistulizing Crohn's disease <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a gastroenterologist</p>	

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [2]

- 6-mercaptopurine (Purinethol)
- Azathioprine (Imuran)
- Corticosteroids (e.g., prednisone, methylprednisolone)
- Methotrexate (Rheumatrex, Trexall)

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to infliximab therapy	

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease or Fistulizing Crohn's Disease [A]
Approval Length	12 month(s)

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none"> • Moderately to severely active Crohn's disease [B] • Fistulizing Crohn's disease <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a gastroenterologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies: [2]</p> <ul style="list-style-type: none"> • 6-mercaptopurine (Purinethol) • Azathioprine (Imuran) • Corticosteroids (e.g., prednisone, methylprednisolone) • Methotrexate (Rheumatrex, Trexall) <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)</p> <ul style="list-style-type: none"> • Avsola • Inflectra 	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a gastroenterologist</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies: [3]</p> <ul style="list-style-type: none"> • 6-mercaptopurine (Purinethol) • Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)] • Azathioprine (Imuran) • Corticosteroids (e.g., prednisone, methylprednisolone) <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)</p> <ul style="list-style-type: none"> • Avsola • Inflectra 	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to infliximab therapy</p>	

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a gastroenterologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following conventional therapies: [3]</p> <ul style="list-style-type: none"> • 6-mercaptopurine (Purinethol) • Aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)] • Azathioprine (Imuran) • Corticosteroids (e.g., prednisone, methylprednisolone) <p style="text-align: center;">AND</p>	

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis Rheumatoid Arthritis (RA)

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active RA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - One of the following:

3.1 Patient is receiving concurrent therapy with methotrexate (Rheumatrex, Trexall)

OR

3.2 Trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex, Trexall)

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to infliximab therapy	

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of moderately to severely active RA	
AND	

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - One of the following:

3.1 Patient is receiving concurrent therapy with methotrexate (Rheumatrex, Trexall)

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to methotrexate (Rheumatrex, Trexall)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.
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Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of active ankylosing spondylitis	

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [4]

AND

4 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis Ankylosing Spondylitis (AS)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis Ankylosing Spondylitis (AS)

Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to two NSAIDs (e.g., diclofenac, ibuprofen, indomethacin, meloxicam, naproxen) [4]</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)</p> <ul style="list-style-type: none"> • Avsola • Inflectra 	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

AND

3 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis Psoriatic Arthritis (PsA)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of active PsA</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Rheumatologist <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)</p> <ul style="list-style-type: none"> • Avsola • Inflectra 	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - Prescribed by or in consultation with a dermatologist

AND

3 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis | Plaque Psoriasis

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy as evidenced by ONE of the following: [8]

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis | Plaque Psoriasis

Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a dermatologist</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)</p> <ul style="list-style-type: none"> • Avsola • Inflectra 	
Notes	*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [5-7]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of sarcoidosis</p>	

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate [Rheumatrex, Trexall], Cytosan [cyclophosphamide], or Imuran [azathioprine])

AND

5 - Trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [5-7]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis

Diagnosis Sarcoidosis [Off-label] [5-7]

Approval Length 12 month(s)

Guideline Type Non Formulary

Approval Criteria

1 - Diagnosis of sarcoidosis

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Dermatologist
- Ophthalmologist

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one corticosteroid (e.g., prednisone)

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one immunosuppressant (e.g., methotrexate [Rheumatrex, Trexall], Cytoxan [cyclophosphamide], or Imuran [azathioprine])

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*: (Applies to Infliximab, Remicade and Renflexis only)

- Avsola
- Inflectra

Notes

*Includes attestation that a total of two infliximab products have already been tried in the past, and the patient should not be made to try a third infliximab product.

3 . Endnotes

- A. Per expert consultant, it is acceptable to combine the Crohn's disease criteria with the fistulizing Crohn's disease criteria, and remove any age requirements in order to receive Remicade. Patients should still be seen by a gastroenterologist and only be required to fail one of four treatment options: corticosteroids, 5-ASA, immunomodulators, or antibiotics. Requiring failure to more than 1 drug would not be appropriate as this would cause treatment delay and disease progression.
- B. In the Remicade clinical study, moderate to severely active Crohn's disease was defined as a Crohn's Disease Activity Index (CDAI), greater than or equal to 220 and less than or equal to 400, inclusive. [1]

4 . References

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA. May 2020.
2. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113:481-517.
3. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114:384-413.
4. Ward MM, Deodhar A, Gensler LS, et al. 2019 update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. 2019;71(10):1599-1613.
5. DRUGDEX System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 7, 2020.
6. Baughman RP, Drent M, Kavuru M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement *Am J Respir Crit Care Med*. 2006 Oct 1;174(7):795-802.
7. Rossman M, Newman LS, Baughman RP, et al. A double-blinded, randomized, placebo-controlled trial of infliximab in subjects with active pulmonary sarcoidosis. *Sarcoidosis Vasc Diffuse Lung Dis*. 2006;23(3):201-8.
8. Per clinical consult with dermatologist. June 26, 2019.

9. Inflectra prescribing information. Hospira. Lake Forest, IL. June 2021.
10. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. February 2021.
11. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. December 2019.
12. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.

Ingrezza (valbenazine)

Prior Authorization Guideline

Guideline Name	Ingrezza (valbenazine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Ingrezza (valbenazine)
Tardive Dyskinesia Indicated for the treatment of adults with tardive dyskinesia.

2 . Criteria

Product Name: Ingrezza	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderate to severe tardive dyskinesia [A]	

AND

2 - One of the following [3, B]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist

Product Name: Ingrezza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

- A. Patients were included in the pivotal randomized, double-blind, placebo-controlled trial of Ingrezza if they had moderate to severe tardive dyskinesia as determined by clinical observation (qualitative assessment). [1, 2]

- B. Verified with consultant that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [4]

4 . References

1. Ingrezza Prescribing Information. Neurocrine Biosciences, Inc. San Diego, CA. April 2021.
2. Hauser RA, Factor SA, Marder SR, et al. KINECT 3: A phase 3 randomized, double-blind, placebo-controlled trial of valbenazine for tardive dyskinesia. *Am J Psychiatry*. 2017 May 1;174(5):476-484.
3. Waln O, Jankovic J. An update on tardive dyskinesia: from phenomenology to treatment. *Tremor Other Hyperkinet Mov (N Y)* 2013 Jul 12;3. pii: tre-03-161-4138-1.
4. Per clinical consult with psychiatrist, June 9, 2017.

Inlyta (axitinib)

Prior Authorization Guideline

Guideline Name	Inlyta (axitinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Inlyta (axitinib)
Advanced Renal Cell Carcinoma Indicated in combination with avelumab or pembrolizumab, for the first-line treatment of patients with advanced renal cell carcinoma (RCC). It is also indicated as a single agent, for the treatment of advanced RCC after failure of one prior systemic therapy.

2 . Criteria

Product Name: Inlyta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - One of the following:

3.1 Used as first-line treatment in combination with one of the following for clear cell renal cell carcinoma^{**}: [2]

- avelumab*
- pembrolizumab*

OR

3.2 Used after failure of one prior systemic therapy (e.g., chemotherapy) for clear cell renal cell carcinoma^{**} [2]

OR

3.3 One of the following:

3.3.1 Both of the following: [2]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.3.2 For continuation of prior therapy

AND

4 - Prescribed by or in consultation with an oncologist

Notes

*This product may require prior authorization.
***Criterion is part of FDA-approved label

Product Name: Inlyta

Approval Length

12 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Inlyta Prescribing Information. Pfizer Labs. New York, NY. September 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.4.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed May 3, 2023.

Inrebic (fedratinib)

Prior Authorization Guideline

Guideline Name	Inrebic (fedratinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Inrebic (fedratinib)
Myelofibrosis Indicated for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

2 . Criteria

Product Name: Inrebic	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of one of the following:	

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Inrebic	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)</p>	

3 . References

1. Inrebic Prescribing Information. Celgene Corporation. Summit, NJ. August 2019.

Prior Authorization Guideline

Guideline Name	Insomnia Agents
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Guideline Note:

Effective Date:	10/15/2023
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1 . Indications

Drug Name: Quviviq (daridorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.
Drug Name: Belsomra (suvorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Dayvigo (lemborexant)
Insomnia Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

2 . Criteria

Product Name: Quviviq	
Approval Length	12 month(s)

Guideline Type	Step Therapy
<p data-bbox="190 352 440 386">Approval Criteria</p> <p data-bbox="190 422 1312 485">1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p data-bbox="776 558 846 592" style="text-align: center;">AND</p> <p data-bbox="190 663 516 697">2 - ONE of the following:</p> <p data-bbox="212 730 1097 764">2.1 If the patient is less than 65 years of age, BOTH of the following:</p> <p data-bbox="190 798 1409 861">2.1.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to ONE of the following:</p> <ul data-bbox="245 898 431 968" style="list-style-type: none">• Belsomra*• Dayvigo* <p data-bbox="776 1041 846 1075" style="text-align: center;">AND</p> <p data-bbox="190 1146 1414 1209">2.1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:</p> <ul data-bbox="245 1247 529 1514" style="list-style-type: none">• eszopiclone• zaleplon• zolpidem• zolpidem ER• triazolam• temazepam• generic ramelteon• doxepin <p data-bbox="784 1587 837 1621" style="text-align: center;">OR</p> <p data-bbox="190 1692 1406 1755">2.2 If the patient is 65 years of age and older, trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:</p> <ul data-bbox="245 1793 529 1892" style="list-style-type: none">• generic ramelteon• Belsomra*• Dayvigo*	

<ul style="list-style-type: none"> doxepin 	
Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Belsomra and brand Dayvigo

Product Name: Belsomra, Dayvigo	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> doxepin eszopiclone temazepam zaleplon zolpidem zolpidem ER 	

3 . References

1. Edluar Prescribing Information. Meda Pharmaceuticals Inc. Somerset, NJ. September 2021.
2. Zolpimist Prescribing Information. Aytu Bioscience, Inc. Englewood, CO. August 2019.
3. Ambien Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
4. Ambien CR Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
5. Quviviq Prescribing Information. Idorsia Pharmaceuticals US Inc. Radnor, PA. April 2022.
6. Belsomra Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. May 2022.
7. Dayvigo Prescribing Information. Eisai, Inc. Nutley, NJ. January 2023.

8. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc* 00:1-21, 2019. Available at <https://www.uclahealth.org/geriatrics/workfiles/education/clinical-skills/handouts/Education-Updated-Beers-List-2019.pdf>. Accessed May 9, 2022.
9. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: An American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349. Available at <https://jcsm.aasm.org/doi/10.5664/jcsm.6470>. Accessed May 9, 2022.
10. UpToDate. Overview of the Treatment of Insomnia in Adults. Available at https://www.uptodate.com/contents/overview-of-the-treatment-of-insomnia-in-adults?search=insomnia&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed March 28, 2023.
11. Zolpidem Prescribing Information. Almatica Pharma LLC. Morristown, NJ. May 2023.

Prior Authorization Guideline

Guideline Name	Interstitial Lung Disease (ILD) Agents
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Esbriet (pirfenidone)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of idiopathic pulmonary fibrosis (IPF).
Drug Name: Ofev (nintedanib)
Idiopathic Pulmonary Fibrosis Indicated for the treatment of idiopathic pulmonary fibrosis (IPF). Systemic Sclerosis-associated Interstitial Lung Disease Indicated for slowing the rate of decline in pulmonary function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD). Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype Indicated for the treatment of chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.

2 . Criteria

Product Name: Brand Esbriet, Generic pirfenidone, Ofev	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by both of the following: [3]</p> <p>1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following:</p> <p>1.2.1 In patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF</p> <p style="text-align: center;">OR</p> <p>1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a pulmonologist</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following (applies to BRAND Esbriet only):</p> <p>3.1 Trial and failure or intolerance to generic pirfenidone</p>	

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Ofev	
Diagnosis	Systemic Sclerosis-associated Interstitial Lung Disease (SSc-ILD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: [5-6]</p> <p>1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following:</p> <p>1.2.1 In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (e.g., fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on high-resolution computed tomography (HRCT) revealing SSc-ILD or probable SSc-ILD</p> <p style="text-align: center;">OR</p>	

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD

AND

2 - Prescribed by or in consultation with a pulmonologist

Product Name: Ofev	
Diagnosis	Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic fibrosing interstitial lung disease

AND

2 - Patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features

AND

3 - Disease has a progressive phenotype as observed by one of the following:

- Decline of forced vital capacity (FVC)
- Worsening of respiratory symptoms
- Increased extent of fibrosis seen on imaging

AND

4 - Prescribed by or in consultation with a pulmonologist

Product Name: Brand Esbriet, Generic pirfenidone	
Diagnosis	Idiopathic Pulmonary Fibrosis (IPF)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following (applies to BRAND Esbriet only):</p> <p> 2.1 Trial and failure or intolerance to generic pirfenidone</p> <p style="text-align: center;">AND</p> <p> 2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium 	

Product Name: Ofev	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Esbriet prescribing information. Genentech, Inc. South San Francisco, CA. December 2020.
2. Ofev prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. November 2020.
3. Raghu G, Collard HR, Egan JJ, et al. Official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. *Am J of Respir Crit Care Med.* 2011;183:788-824.
4. Raghu G, Rochweg B, Zhang Y, et al. An Official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis, an update of the 2011 clinical practice guideline. *Am J Respir Crit Care Med.* 2015;192(2):e3-e19.
5. Fischer A, Swigris JJ, Groshong SD, et al. Clinically significant interstitial lung disease in limited scleroderma: histopathology, clinical features, and survival. *Chest* 2008; 134:601.
6. UptoDate [internet database]. Waltham, MA. UpToDate, Inc. Clinical manifestations, evaluation, and diagnosis of interstitial lung disease in systemic sclerosis (scleroderma). Available by subscription at: <https://www.uptodate.com>. Accessed November 18, 2020.
7. Pirfenidone Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, New Jersey. August 2022.

Iressa (gefitinib)

Prior Authorization Guideline

Guideline Name	Iressa (gefitinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Iressa (gefitinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Limitation of Use: Safety and efficacy of Iressa have not been established in patients with metastatic NSCLC whose tumors have EGFR mutations other than exon 19 deletions or exon 21 (L858R) substitution mutations.

2 . Criteria

Product Name: Brand Iressa, Generic gefitinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Trial and failure, contraindication or intolerance to generic gefitinib (Applies to Brand Iressa only)

Product Name: Brand Iressa, Generic gefitinib

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Iressa Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2021.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2014. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 27, 2023.

Prior Authorization Guideline

Guideline Name	Isotretinoin
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Guideline Note:

Effective Date:	3/1/2022
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1 . Indications

Drug Name: Isotretinoin (Absorica, Absorica LD, Accutane, Amnesteem, Claravis, Myorisan, and Zenatane)

Severe recalcitrant nodular acne Indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse reactions associated with its use, isotretinoin should be reserved for patients with multiple severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those female patients who are not pregnant, because isotretinoin can cause severe birth defects. Limitations of Use: A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience with isotretinoin has shown that patients may continue to improve following treatment with isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

2 . Criteria

Product Name: Absorica, Generic isotretinoin, Absorica LD, Accutane, Amnesteem, Claravis, Myorisan, or Zenatane

Approval Length | 5 Months [1-4, 10]

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of acne [1-4, 9-11, D]

AND

2 - One of the following:

2.1 Prescribed by a dermatologist

OR

2.2 Trial and failure, contraindication, or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens:

2.2.1 One topical retinoid or retinoid-like agent [e.g., Retin-A/Retin-A Micro (tretinoin)] [5, 7]

AND

2.2.2 Combination therapy with benzoyl peroxide and one of the following: [5-8]

2.2.2.1 Oral antibiotic [e.g., Ery-Tab (erythromycin), Minocin (minocycline)] [1-4, 7, 10, A]

OR

2.2.2.2 If oral antibiotics are not indicated, a topical antibiotic [e.g., Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)] [5-7]

AND

3 - Trial and failure, contraindication, or intolerance to **THREE** of the following (applies to brand* Absorica and Absorica LD only):

- Amnesteem
- Accutane
- Claravis
- Myorisan
- Zenatane
- Generic isotretinoin^

Notes	* Recommended administration for brand Absorica and Absorica LD is with or without meals; the other products are recommended to be administered with food - there is not data supporting a requirement of a meal high in fat. Pharmacokinetic differences between Absorica, Absorica LD and other formulary agents is not considered a true contraindication or reason for intolerance and is not an acceptable reason for approval.
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Product Name: Absorica, Generic isotretinoin, Absorica LD, Accutane, Amnesteem, Claravis, Myorisan, or Zenatane	
Diagnosis	Persistent or Recurring Acne After 2 Months Off Therapy
Approval Length	5 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria 1 - After more than 2 months off therapy, persistent or recurring acne is still present [1-4, 9-11, B, D]	
Notes	Authorization will be given only by clinical pharmacist review for up to 5 months.

Product Name: Absorica, Generic isotretinoin, Absorica LD, Accutane, Amnesteem, Claravis, Myorisan, or Zenatane	
Diagnosis	Dose Titration

Approval Length	1 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Confirmation that the cumulative dose is less than 150 mg/kg (there is little therapeutic benefit to be gained by increasing the cumulative dose beyond 150 mg/kg) [1-4, 9, 10, C]*	
Notes	Authorization will be given only by clinical pharmacist review for 1 month to allow for titration up to the target dose *See background section for dosing regimens

3 . Background

Benefit/Coverage/Program Information				
Dosing by Body Weight (based on administration with food):				
Body Weight		Daily Dose		
Kg	Lbs	0.5 mg/kg/day	1 mg/kg/day	2 mg/kg/day
40	88	20	40	80
50	110	25	50	100
60	132	30	60	120
70	154	35	70	140
80	176	40	80	160
90	198	45	90	180
100	220	50	100	200

4 . Endnotes

- A. Isotretinoin use has been associated with a number of cases of pseudotumor cerebri (benign intracranial hypertension), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided. [1-4, 10]
- B. Experience has shown that patients may continue to improve while off isotretinoin therapy. After a period of 2 months or more 'off therapy', and if warranted by persistent or

recurring severe nodular acne, a second course of therapy of isotretinoin may be initiated. [1-4, 10]

- C. According to the AAD, acne experts feel strongly that initial flaring can be decreased with a beginning dose of 0.5 mg/kg/day or less. Lower doses can be used for longer periods of time with a total cumulative dose of 120 to 150 mg/kg. [9]
- D. Isotretinoin has been effective in treating mild-to-moderate acne vulgaris in a double-blind, placebo-controlled study (n=127), for acne in a study of 156 patients, and for mild-to-moderate acne vulgaris in a double-blind study (n=268) [11]. Additionally, the American Academy of Dermatology recommends isotretinoin for the treatment of severe nodular acne, and states that it may be appropriate for the treatment of moderate acne that is treatment-resistant or for the management of acne that is producing physical scarring and/or psychosocial distress [9].

5 . References

1. Absorica/Absorica LD Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. January 2020.
2. Amnesteem Prescribing Information. Mylan Pharmaceuticals, Inc. Morgantown, WV. August 2019.
3. Claravis Prescribing Information. Teva Pharmaceutical USA, Inc. North Wales, PA. May 2018.
4. Myorisan Prescribing Information. VersaPharm, Inc. Lake Forest, IL. October 2018.
5. Haider A, Shaw JC. Treatment of acne vulgaris. *JAMA*. 2004;292(6):726-735.
6. Gollnick H, Cunliffe W, Berson D, et al. Management of Acne: A report from a global alliance to improve outcomes in acne. *J Am Acad Dermatol*. 2003;49(suppl 1):S1-38.
7. Goldsmith LA, Bologna JL, Callen JP, et al. American Academy of Dermatology consensus conference on the safe and optimal use of isotretinoin: Summary and recommendations. *J Am Acad Dermatol*. 2004;50:900-6.
8. Leyden JJ. A review of the use of combination therapies for the treatment of acne vulgaris. *J Am Acad Dermatol*. 2003;49(3):S200-S210.
9. American Academy of Dermatology. Clinical Guidelines of Care for Acne Vulgaris Management. Available at: <http://www.aad.org/education/clinical-guidelines>. Accessed January 22, 2020.
10. Zenatane Prescribing Information. Dr. Reddy's Laboratories Limited. Bachupally, India. January 2019.
11. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: <http://www.thomsonhc.com/>. Accessed January 7, 2021.
12. Accutane Prescribing Information. JG Pharma Inc. Scottsdale, AZ. January 2021.

Isturisa (osilodrostat)

Prior Authorization Guideline

Guideline Name	Isturisa (osilodrostat)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Isturisa (osilodrostat)
Cushing's Disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

2 . Criteria

Product Name: Isturisa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Cushing's disease	

AND

2 - One of the following:

- Patient is not a candidate for pituitary surgery
- Pituitary surgery has not been curative for the patient

AND

3 - Trial and failure for a minimum of 90 days, contraindication or intolerance to oral ketoconazole [A]

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Isturisa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)	

3 . Endnotes

- A. Per feedback from consultant, determining efficacy of ketoconazole therapy is difficult to determine as multiple dose adjustments often need to be made depending on patient's response. Consultant recommends failure to respond to therapy be defined as requiring more than 3-4 dose adjustments or no response after 4 months. [4]

4 . References

1. Isturisa prescribing information. Recordati Rare Diseases Inc. Lebanon, NJ. May 2020.
2. Pivonello R, Fleseriu M, Newell-Price J, et al. Osilodrostat provides clinical benefit over 48 weeks in patients with Cushing disease: results from the LINC 3 study. *Endocr Abstr.* 2019. <https://doi.org/10.1530/endoabs.63.OC3.1>. Accessed May 16, 2020.
3. DRUGDEX [Internet database]. Greenwood Village, CO: Thomson MICROMEDEX, updated periodically. Accessed September 1, 2020.
4. Per clinical consult with endocrinologist, July 13, 2020.

Prior Authorization Guideline

Guideline Name	Jakafi (ruxolitinib)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Jakafi (ruxolitinib)
<p>Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults.</p> <p>Polycythemia Vera Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.</p> <p>Acute Graft Versus Host Disease Indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.</p> <p>Chronic Graft Versus Host Disease Indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.</p>

2 . Criteria

Product Name: Jakafi

Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none"> • Primary myelofibrosis • Post-polycythemia vera myelofibrosis • Post-essential thrombocythemia myelofibrosis <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of polycythemia vera [1]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]</p> <p style="text-align: center;">AND</p>	

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Jakafi

Diagnosis Myelofibrosis, Polycythemia Vera

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Jakafi therapy (e.g., spleen volume reduction, symptom improvement, hematocrit control)

Notes If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 2-month authorization should be issued one time for Jakafi gradual therapy discontinuation.

Product Name: Jakafi

Diagnosis Acute Graft Versus Host Disease

Approval Length 6 Month(s) [C]

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of acute graft-versus-host disease

AND

2 - Disease is steroid-refractory

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic graft-versus-host disease</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Hematologist• Oncologist	

- Physician experienced in the management of transplant patients

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . Endnotes

- A. Jakafi should be discontinued after 6 months if there is no spleen size reduction or symptom improvement since initiation of therapy. [1]
- B. The initial authorization duration of 8 months is based on clinical trials (primary endpoint of hematocrit control and spleen volume reduction was evaluated at 32 weeks). [1]
- C. Authorization duration of 6 months is based median time from response to death or need for new therapy for acute GVHD in clinical trials (173 days). Additionally, tapering of Jakafi may be considered after 6 months of treatment in patients with response who have discontinued therapeutic doses of corticosteroids. [1]

4 . References

1. Jakafi Prescribing Information. Incyte Corp. Wilmington, DE. January 2023.

Jaypirca (pirtobrutinib)

Prior Authorization Guideline

Guideline Name	Jaypirca (pirtobrutinib)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Jaypirca (pirtobrutinib)
Mantle Cell Lymphoma (MCL) Indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton Tyrosine Kinase (BTK) inhibitor. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 . Criteria

Product Name: Jaypirca	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of mantle cell lymphoma (MCL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)] [1, 3]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Jaypirca

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Jaypirca Prescribing Information. Lilly USA, LLC. Indianapolis, IN. January 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 8, 2023.
3. Clinical Consult with an oncologist March 9, 2023.

Jevtana (cabazitaxel)

Prior Authorization Guideline

Guideline Name	Jevtana (cabazitaxel)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Jevtana	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - All of the following:</p> <p>1.1 Diagnosis of metastatic castration-resistant prostate cancer</p> <p style="text-align: center;">AND</p> <p>1.2 Used in combination with prednisone</p>	

AND

1.3 Patient has been previously treated with a docetaxel-containing regimen

AND

1.4 Prescribed by or in consultation with an oncologist

Product Name: Jevtana

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease [3]

2 . References

1. Jevtana Prescribing Information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ. January 2018.

Joenja (leniolisib)

Prior Authorization Guideline

Guideline Name	Joenja (leniolisib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Joenja (leniolisib)
Activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome Indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3K δ) syndrome (APDS) in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name: Joenja	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of activated phosphoinositide 3-kinase delta syndrome (APDS)	

AND

2 - Molecular genetic testing confirms mutations in the PIK3CD or PIK3R1 gene

AND

3 - Patient is 12 years of age or older

AND

4 - Patient weighs greater than or equal to 45kg

AND

5 - Both of the following:

- Presence of nodal and/or extranodal proliferation (e.g., lymphadenopathy, splenomegaly, hepatomegaly)
- Presence of other clinical findings and manifestations consistent with APDS (e.g., recurrent sino-pulmonary infections, bronchiectasis, enteropathy)

AND

6 - Trial and failure, contraindication, or intolerance to at least one standard of care treatment for APDS (e.g., Immunoglobulin replacement therapy, antimicrobial prophylaxis [e.g., azithromycin, bactrim], rituximab, tacrolimus, etc.) [3]

AND

7 - Prescribed by or in consultation with one of the following:

- Hematologist
- Immunologist

Product Name: Joenja	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased severity or frequency of infections/hospitalizations)</p>	

3 . Endnotes

- A. Per consult with specialist, extending initial authorization to 6 months will give providers more time to assess efficacy and see those surrogate outcomes such as reduced lymph node size. [2]

4 . References

1. Joenja Prescribing Information. Pharming Technologies, Inc. Foster City, CA. March 2023.
2. Per clinical consultation with allergist/immunologist specialist, May 10, 2023.
3. Rao VK, Webster S, Šedivá A, et al. Randomized, Placebo-Controlled, Phase 3 Trial of PI3K δ Inhibitor Leniolisib for Activated PI3K δ Syndrome. Blood. Published online November 18, 2022.

Prior Authorization Guideline

Guideline Name	Jublia (efinaconazole), Kerydin (tavaborole) - Non Formulary
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Guideline Note:

Effective Date:	5/15/2022
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1 . Indications

Drug Name: Jublia (efinaconazole)
Onychomycosis Indicated for the topical treatment of onychomycosis of the toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes.
Drug Name: Kerydin (tavaborole) topical solution
Onychomycosis Indicated for the topical treatment of onychomycosis of the toenails due to Trichophyton rubrum or Trichophyton mentagrophytes.

2 . Criteria

Product Name: Jublia, Brand Kerydin, Generic tavaborole	
Diagnosis	Onychomycosis
Approval Length	48 Weeks [1-4]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by ONE of the following: [4, 5]

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail [5]

AND

5 - Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail)

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ciclopirox

OR

6.2 Patient is 6 to 12 years of age

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ONE of the following oral antifungal agents:

- itraconazole
- terbinafine
- griseofulvin

3 . References

1. Jublia prescribing information. Bausch Health Companies Inc. Bridgewater, NJ. July 2020.
2. Kerydin prescribing information. PharmaDerm, a division of Fougera Pharmaceuticals, Inc. Melville, NY. August 2018.
3. Tavaborole prescribing information. Alembic Pharmaceuticals, Inc. Bridgewater, NJ. October 2020.
4. Aggarwal R, Targotra M, Kumar B, Sahoo PK, Chauhan MK. Treatment and management strategies of onychomycosis. J Mycol Med. 2020 Jun;30(2):100949.
5. Leung AKC, Lam JM, Leong KF, et al. Onychomycosis: An Updated Review. Recent Pat Inflamm Allergy Drug Discov. 2020;14(1):32-45.

Juxtapid (lomitapide)

Prior Authorization Guideline

Guideline Name	Juxtapid (lomitapide)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Juxtapid (lomitapide)
Homozygous familial hypercholesterolemia (HoFH) Indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). Limitations of use: (1) The safety and effectiveness of Juxtapid have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). (2) The effect of Juxtapid on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name: Juxtapid	
Approval Length	6 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [1-3]

1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated/pre-treatment LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe) [A]

OR

2.2 Patient has an inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Trial and failure, contraindication, or intolerance to Repatha therapy

AND

4 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

Product Name: Juxtapid	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p>OR</p> <p>1.2 Patient has an inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p>AND</p> <p>2 - Reduction in LDL-C from baseline while on therapy</p>	

AND

3 - Prescribed by or in consultation with one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist

AND

4 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

3 . Endnotes

- A. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; $p = 0.016$; number needed to treat [NNT] = 50). [5] The effect of lomitapide on cardiovascular morbidity and mortality has not been determined. [1]
- B. Lipid specialists are physicians certified by the American Board of Clinical Lipidology (ABCL) or the Accreditation Council for Clinical Lipidology (ACCL). [6, 7] In the opinion of the ACC expert consensus writing committee, lomitapide is best administered under the care of a lipid specialist. [8]
- C. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [4]

4 . References

1. Juxtapid Prescribing Information. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2020.
2. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. *Atherosclerosis*. 2012;223:262-8.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J*. 2014;35:2146-57.

4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73:e285-e350.
5. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. *N Engl J Med*. 2015;372:2387-97.
6. American Board of Clinical Lipidology website. www.lipidboard.org. Accessed September 3, 2020.
7. Accreditation Council for Clinical Lipidology website. www.lipidspecialist.org. Accessed September 3, 2020.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol*. 2017;70:1785-1822.

Prior Authorization Guideline

Guideline Name	Kalydeco (ivacaftor)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Kalydeco (ivacaftor)
<p>Cystic fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients age 1 month and older who have one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.</p>

2 . Criteria

Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data* as detected by an FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 1 month of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a CF care center
- Pulmonologist

Notes	*Please consult Background section for table of CFTR gene mutations responsive to Kalydeco.
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Product Name: Kalydeco	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response (i.e., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}], decreased number of pulmonary exacerbations) to therapy [A]</p>	

3 . Background

Clinical Practice Guidelines				
CFTR Gene Mutations that are Responsive to Kalydeco [1]				
*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 1/6/23]				
List of CFTR Gene Mutations that Produce CFTR Protein and are Responsive to KALYDECO				
<i>711+3A→G *</i>	<i>F311del</i>	<i>I148T</i>	<i>R75Q</i>	<i>S589N</i>
<i>2789+5G→A *</i>	<i>F311L</i>	<i>I175V</i>	<i>R117C *</i>	<i>S737F</i>
<i>3272-26A→G *</i>	<i>F508C</i>	<i>I807M</i>	<i>R117G</i>	<i>S945L *</i>
<i>3849+10kbC→T *</i>	<i>F508C;S1251N †</i>	<i>I1027T</i>	<i>R117H *</i>	<i>S977F *</i>
<i>A120T</i>	<i>F1052V</i>	<i>I1139V</i>	<i>R117L</i>	<i>S1159F</i>
<i>A234D</i>	<i>F1074L</i>	<i>K1060T</i>	<i>R117P</i>	<i>S1159P</i>
<i>A349V</i>	<i>G178E</i>	<i>L206W *</i>	<i>R170H</i>	<i>S1251N *</i>
<i>A455E *</i>	<i>G178R *</i>	<i>L320V</i>	<i>R347H *</i>	<i>S1255P *</i>
<i>A1067T</i>	<i>G194R</i>	<i>L967S</i>	<i>R347L</i>	<i>T338I</i>
<i>D110E</i>	<i>G314E</i>	<i>L997F</i>	<i>R352Q *</i>	<i>T1053I</i>
<i>D110H</i>	<i>G551D *</i>	<i>L1480P</i>	<i>R553Q</i>	<i>V232D</i>
<i>D192G</i>	<i>G551S *</i>	<i>M152V</i>	<i>R668C</i>	<i>V562I</i>
<i>D579G *</i>	<i>G576A</i>	<i>M952I</i>	<i>R792G</i>	<i>V754M</i>
<i>D924N</i>	<i>G970D</i>	<i>M952T</i>	<i>R933G</i>	<i>V1293G</i>
<i>D1152H *</i>	<i>G1069R</i>	<i>P67L *</i>	<i>R1070Q</i>	<i>W1282R</i>
<i>D1270N</i>	<i>G1244E *</i>	<i>Q237E</i>	<i>R1070W *</i>	<i>Y1014C</i>
<i>E56K</i>	<i>G1249R</i>	<i>Q237H</i>	<i>R1162L</i>	<i>Y1032C</i>
<i>E193K</i>	<i>G1349D *</i>	<i>Q359R</i>	<i>R1283M</i>	
<i>E822K</i>	<i>H939R</i>	<i>Q1291R</i>	<i>S549N *</i>	
<i>E831X *</i>	<i>H1375P</i>	<i>R74W</i>	<i>S549R *</i>	

** Clinical data exist for these mutations.*

† Complex/compound mutations where a single allele of the CFTR gene has multiple mutations these exist independent of the presence of mutations on the other allele.

4 . Endnotes

- A. The primary efficacy endpoint in both Kalydeco pivotal trials was improvement in lung function as determined by the mean absolute change from baseline in percent predicted pre-dose FEV1 through 24 weeks of treatment. [2]

5 . References

1. Kalydeco Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. May 2023.
2. Ramsey BW, Davies J, McElvaney G, et al. A CFTR potentiator in patients with cystic fibrosis and the G551D mutation. N Engl J Med. 2011;365:1663-1672.

Kerendia (finerenone)

Prior Authorization Guideline

Guideline Name	Kerendia (finerenone)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Kerendia (finerenone)
Chronic Kidney Disease Associated with Type 2 Diabetes Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D).

2 . Criteria

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D)

AND

2 - Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g

AND

3 - Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m²

AND

4 - Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment

AND

5 - One of the following:

5.1 Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following [2]:

- Generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- Generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

Product Name: Kerendia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB

OR

2.2 Patient has a contraindication or intolerance to ACE inhibitors and ARBs

3 . References

1. Kerendia Prescribing Information. Bayer Healthcare Pharmaceuticals Inc. Whippany, NJ. July 2021.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. *Kidney Int.* 2020;98(4S): S1-S115.

Keveyis (dichlorphenamide)

Prior Authorization Guideline

Guideline Name	Keveyis (dichlorphenamide)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Keveyis (dichlorphenamide)
Primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants Indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

2 . Criteria

Product Name: Brand Keveyis, Generic dichlorphenamide	
Approval Length	3 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of one of the following:	

- Primary hyperkalemic periodic paralysis
- Primary hypokalemic periodic paralysis
- Paramyotonia Congenita with periodic paralysis [2]
- Andersen-Tawil syndrome [3]

AND

2 - One of the following [3]:

2.1 Patient has positive genetic panel for periodic paralysis

OR

2.2 One of the following tests demonstrated positive results for periodic paralysis:

- EMG/nerve conduction studies
- Long exercise test
- Muscle biopsy
- Muscle MRI

AND

3 - Patient has distinct, regular episodes of weakness at least once a week [4]

AND

4 - Trial and inadequate response, contraindication or intolerance to acetazolamide [off-label] [5]

AND

5 - Provider attests that other known causes of potassium fluctuations have been excluded (e.g., thyrotoxic periodic paralysis, drugs that cause potassium abnormalities, etc)

AND

6 - One of the following:

6.1 If new to therapy, dose will be initiated at 50mg twice daily

OR

6.2 Medication is being prescribed as continuation of therapy

AND

7 - Prescribed by or in consultation with a neurologist

Product Name: Brand Keveyis, Generic dichlorphenamide	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient demonstrates positive clinical response to therapy as evidenced by a decrease in weekly attack frequency from baseline [4]	

3 . Endnotes

- A. Prescribers should evaluate the patient's response to Keveyis after 2 months of treatment to decide whether treatment should be continued [1]. An additional month is added to the initial authorization duration to allow patient follow-up with the provider.

4 . References

1. Keveyis Prescribing Information. Stonebridge Biopharma; Trevose, PA. November 2019
2. Tawil R, McDermott MP, Brown R Jr, et al. Randomized trials of dichlorphenamide in the periodic paralyses. Working Group on Periodic Paralysis. Ann Neurol. 2000;47(1):46-53.

3. Ciafaloni E, Jackson C, Kincaid J, et al. Primary Periodic Paralysis: The Diagnostic Journey.; 2019. Accessed January 4, 2023. <https://keveyis.com/wp-content/uploads/keveyis-ppp-diagnostic-journey.pdf>
4. Sansone VA, Burge J, McDermott MP, et al. Randomized, placebo-controlled trials of dichlorphenamide in periodic paralysis. *Neurology*. 2016;86(15):1408-1416. doi:10.1212/wnl.0000000000002416
5. Statland JM, Fontaine B, Hanna MG, et al. Review of the Diagnosis and Treatment of Periodic Paralysis. *Muscle & Nerve*. 2017;57(4):522-530. doi:10.1002/mus.26009

Kevzara (sarilumab)

Prior Authorization Guideline

Guideline Name	Kevzara (sarilumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Kevzara (sarilumab)
Rheumatoid Arthritis (RA) Indicated for treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).
Polymyalgia Rheumatica (PMR) Indicated for treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

2 . Criteria

Product Name: Kevzara	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)

- Orencia (abatacept)

OR

4.2 For continuation of prior Kevzara therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Kevzara	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of polymyalgia rheumatica (PMR)</p>	

AND

2 - One of the following:

2.1 Patient has had an inadequate response to corticosteroids (e.g., prednisone)

OR

2.2 Patient cannot tolerate tapering of corticosteroids (e.g., prednisone)

AND

3 - Prescribed by or in consultation with a rheumatologist

Notes	If patient meets criteria above, please approve at GPI-14
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Product Name: Kevzara 200 mg	
Diagnosis	Polymyalgia Rheumatica (PMR)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:	
<ul style="list-style-type: none">• Improvement in symptoms (e.g., pain, stiffness) or lab values (e.g., C-reactive protein) from baseline• Reduced need for corticosteroids (e.g., prednisone)	
Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Kevzara prescribing information. sanofi-aventis U.S. LLC. Bridgewater, NJ. February 2023.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Dejaco C, Singh YP, Perel P, et al. 2015 recommendations for the management of polymyalgia rheumatica: a European League Against Rheumatism/American College of Rheumatology collaborative initiative. 2015;74(10):1799-807.

Kineret (anakinra)

Prior Authorization Guideline

Guideline Name	Kineret (anakinra)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Kineret (anakinra)
<p>Rheumatoid Arthritis (RA) Indicated for the reduction in signs and symptoms and slowing the progression of structural damage in moderately to severely active rheumatoid arthritis (RA), in patients 18 years of age or older who have failed 1 or more disease modifying antirheumatic drugs (DMARDs). Kineret can be used alone or in combination with DMARDs other than tumor necrosis factor (TNF) blocking agents.</p> <p>Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A] Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID).</p> <p>Deficiency of Interleukin-1 Receptor Antagonist (DIRA) Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA).</p> <p>Off Label Uses: Systemic Juvenile Idiopathic Arthritis (SJIA) Has been used for the treatment of systemic juvenile idiopathic arthritis. [7]</p>

2 . Criteria

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active rheumatoid arthritis (RA)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none"> • methotrexate • leflunomide • sulfasalazine <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 All of the following:</p> <p>4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*</p> <ul style="list-style-type: none"> • Cimzia (certolizumab pegol) • Enbrel (etanercept) • Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm • Rinvoq (upadacitinib) • Simponi (golimumab) 	

- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

4.2 For continuation of prior Kineret therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of NOMID has been confirmed by one of the following: [5-6, B]</p> <p style="padding-left: 20px;">2.1 NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3-gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation</p> <p style="text-align: center;">OR</p> <p>2.2 Both of the following:</p> <p style="padding-left: 20px;">2.2.1 Two of the following clinical symptoms:</p> <ul style="list-style-type: none"> • Urticaria-like rash • Cold/stress triggered episodes • Sensorineural hearing loss • Musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia) • Chronic aseptic meningitis • Skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) <p style="text-align: center;">AND</p> <p style="padding-left: 20px;">2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following</p> <ul style="list-style-type: none"> • Allergist/Immunologist • Rheumatologist 	

- Pediatrician

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)</p>	

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active systemic juvenile idiopathic arthritis [7]</p>	

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [7]:

- Minimum duration of a 3-month trial and failure of methotrexate
- Minimum duration of a 1-month trial of a nonsteroidal anti-inflammatory drug (NSAID) (e.g., ibuprofen, naproxen)
- Minimum duration of a 2-week trial of a systemic glucocorticoid (e.g., prednisone)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [7]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in clinical features or symptoms (e.g., pain, fever, inflammation, rash, lymphadenopathy, serositis) from baseline	

3 . Endnotes

- A. Three clinically overlapping, interleukin-1-associated, autoinflammatory disorders are known collectively as the cryopyrin-associated periodic syndromes (CAPS) or cryopyrinopathies: familial cold autoinflammatory syndrome (FCAS), Muckle-Wells

- syndrome (MWS), and neonatal onset multisystem inflammatory disorder (NOMID, also known as chronic infantile neurological cutaneous and articular [CINCA] syndrome). [4]
- B. In addition to clinical symptoms, a diagnosis should be made using a combination of procedures including laboratory assessments, skin biopsy, and genetic testing. [5] Diagnostic criteria developed by a multidisciplinary team of international experts in the care of children and adults with CAPS found that the best diagnosis criteria model included: raised inflammatory markers (CRP/SAA) plus two or more of six CAPS-typical signs/symptoms including (1) urticaria-like rash, (2) cold-triggered episodes, (3) sensorineural hearing loss, (4) musculoskeletal symptoms (arthralgia/arthritis/myalgia), (5) chronic aseptic meningitis, and (6) skeletal abnormalities (epiphyseal overgrowth/frontal bossing). This proposed model had a sensitivity of 81% and a specificity of 94%. It performed equally well for all CAPS subtypes and in subgroups with and without evidence of NLRP3 mutation ($p < 0.001$). [4, 6]

4 . References

1. Kineret Prescribing Information. Swedish Orphan Biovitrum. Stockholm, Sweden. December 2020.
2. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol.* 2021;73(7):1108-23.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
4. Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. UpToDate. Updated June 6, 2017. <http://www.uptodate.com>. Accessed March 19, 2019.
5. Yu JR and Leslie KS. Cryopyrin-associated periodic syndrome: an update on diagnosis and treatment response. *Curr Allergy Asthma Rep.* 2011;11(1):12-20
6. Kuemmerle-Deschner JB, Ozen S, Tyrrell PN, et al. Diagnostic criteria for cryopyrin-associated periodic syndrome (CAPS). *Ann Rheum Dis.* 2017 Jun;76(6):942-947.
7. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol.* 2022;74(4):553-569.

Kisqali (ribociclib), Kisqali Femara Co-Pack (letrozole and ribociclib)

Prior Authorization Guideline

Guideline Name	Kisqali (ribociclib), Kisqali Femara Co-Pack (letrozole and ribociclib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Kisqali (ribociclib)
Breast cancer Indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic cancer in combination with one of the following: (1) an aromatase inhibitor as initial endocrine-based therapy, (2) fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men.
Drug Name: Kisqali Femara Co-Pack (letrozole and ribociclib)
Breast cancer Indicated as initial endocrine-based therapy for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.

2 . Criteria

Product Name: Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Kisqali, Kisqali Femara Co-Pack	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Kisqali prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. December 2021.
2. Kisqali Femara Co-Pack prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. December 2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v4.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. (Accessed August 4, 2022).

Korlym (mifepristone)

Prior Authorization Guideline

Guideline Name	Korlym (mifepristone)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Korlym	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids) [A]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p>	

- Diagnosis of type 2 diabetes mellitus
- Diagnosis of glucose intolerance

AND

3 - Patient has hyperglycemia that is secondary to hypercortisolism

AND

4 - One of the following:

- Patient has failed surgery
- Patient is not a candidate for surgery

AND

5 - Prescribed by or in consultation with an endocrinologist

AND

6 - Patient is not pregnant

Product Name: Korlym	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of one of the following:</p> <ul style="list-style-type: none"> • Patient has improved glucose tolerance while on Korlym therapy • Patient has stable glucose tolerance while on Korlym therapy 	

2 . Endnotes

- A. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome. [1]

3 . References

- 1. Korlym Prescribing Information. Corcept Therapeutics Inc.; Menlo Park, CA. May 2017.

Koselugo (selumetinib)

Prior Authorization Guideline

Guideline Name	Koselugo (selumetinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Koselugo (selumetinib)
Neurofibromatosis Type 1 Indicated for the treatment of pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN)

2 . Criteria

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of neurofibromatosis type 1

AND

2 - Patient has plexiform neurofibromas that are both of the following:

- Inoperable [B]
- Causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment)

AND

3 - One of the following:

3.1 Patient is less than 18 years of age

OR

3.2 Both of the following:

- Patient is 18 years of age or older
- Patient is continuing therapy [C]

AND

4 - Patient is able to swallow a capsule whole

AND

5 - Prescribed by or in consultation with one of the following:

- Oncologist
- Neurologist

Product Name: Koselugo

Diagnosis	Neurofibromatosis Type 1
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of disease progression while on therapy</p>	

3 . Endnotes

- A. The initial authorization duration of 6 months is to allow for assessment of adverse reactions (e.g., cardiomyopathy) without interruption of therapy [1,2].
- B. Inoperable plexiform neurofibromas are defined as those that could not be completely removed without risk for substantial morbidity due to encasement of, or close proximity to, vital structures, invasiveness, or high vascularity of the PN [1].
- C. It is the recommendation of the consultant that the medication should not be discontinued due to patient's age [2].

4 . References

1. Koselugo prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2020.
2. Per clinical consult with oncologist, May 27, 2020.

Krazati (adagrasib)

Prior Authorization Guideline

Guideline Name	Krazati (adagrasib)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Krazati (adagrasib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of a clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Krazati	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy)

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Krazati	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Krazati Prescribing Information. Mirati Therapeutics, Inc. San Diego, CA. December 2022.

Krystexxa (pegloticase)

Prior Authorization Guideline

Guideline Name	Krystexxa (pegloticase)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Krystexxa (pegloticase)
Refractory gout Indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. Gout refractory to conventional therapy occurs in patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated. Important Limitations of Use: Krystexxa is not recommended for the treatment of asymptomatic hyperuricemia.

2 . Criteria

Product Name: Krystexxa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gout

AND

2 - Trial and failure, contraindication, or intolerance to maximum recommended doses to both of the following conventional therapies: [A]

- Xanthine oxidase inhibitor (i.e., allopurinol, febuxostat)
- Uricosuric agent (e.g., probenecid)

AND

3 - One of the following:

- History of at least two gout flares in the previous 12 months
- At least 1 gouty tophus

AND

4 - Prescribed by or in consultation with a rheumatologist or nephrologist

Product Name: Krystexxa

Approval Length	12 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as demonstrated by both of the following:

- Serum urate level has decreased since initiating therapy
- Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life)

3 . Endnotes

- A. Additional inclusion criteria in pivotal trials were as follows: Contraindication to treatment with allopurinol or history of failure to normalize serum uric acid despite 3 or more months of treatment with the maximum medically appropriate allopurinol dose (determined by the treating physician) [2]. Febuxostat is another first-line pharmacologic agent for the treatment of gout [3]
- B. The efficacy and safety profile of long-term pegloticase treatment (mean follow-up of 2.5 years) has been shown to be consistent with that observed in the 6 month pivotal trials. [4]

4 . References

1. Krystexxa Prescribing Information. Horizon Therapeutics, Inc. Deerfield, IL. November 2022.
2. Sundy JS, Baraf HS, Yood RA, et al. Efficacy and tolerability of pegloticase for the treatment of chronic gout in patients refractory to conventional treatment: two randomized controlled trials. JAMA. 2011;306(7):711-20.
3. Fitzgerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology Guideline for Management of Gout. Arthritis Care Res (Hoboken). 2020 Jun;72(6):774-60.
4. Becker MA, Baraf HS, Yood RA. Long-term safety of pegloticase in chronic gout refractory to conventional treatment. Ann Rheum Dis. 2013;72(9):1469-74.

Kuvan (sapropterin dihydrochloride)

Prior Authorization Guideline

Guideline Name	Kuvan (sapropterin dihydrochloride)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Kuvan (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

2 . Criteria

Product Name: Brand Kuvan	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of phenylketonuria (PKU)	

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]

AND

4 - Trial and failure or intolerance to generic sapropterin

Product Name: Brand Kuvan

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

Product Name: Generic sapropterin	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of phenylketonuria (PKU)</p> <p style="text-align: center;">AND</p> <p>2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]</p>	

Product Name: Generic sapropterin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]</p> <p style="text-align: center;">AND</p> <p>2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]</p>	

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

3 . Endnotes

- A. All patients who are treating phenylketonuria (PKU) with Kuvan (sapropterin dihydrochloride) should also be treated with a phenylalanine (Phe) restricted diet [1].
- B. Kuvan (sapropterin dihydrochloride) was evaluated in a phase III, randomized, placebo-controlled trial to determine its efficacy in reducing blood Phe concentration [2]. The primary endpoint was mean change from baseline in concentration of Phe in blood after 6 weeks. The mean age was 20 years. Results showed that after 6 weeks of therapy, patients who received Kuvan (sapropterin dihydrochloride) (n=41) had a decrease in mean blood Phe of 236 micromol/L, compared with a 3 micromol/L increase in the placebo group (n=47; p less than 0.0001).
- C. Patients should be evaluated for response to therapy after treatment with Kuvan at 20mg/kg per day for a period of one month [1]. The 2 month initial authorization duration allows for patients who start on 10mg/kg per day for the first month, to increase their dose to 20mg/kg per day for an additional month prior to evaluation of response.
- D. In clinical trials, response to therapy was defined as greater than or equal to 30% decrease in blood Phe from baseline [1]. The American College of Medical Genetics and Genomics guideline notes a significant decline in blood Phe is expected in Kuvan (sapropterin dihydrochloride) responders once treatment is started [3]. A reduction of 30% is most often cited in the literature as evidence of effective Phe reduction.
- E. Phe blood levels should be checked after one week of Kuvan treatment and periodically after that to assess blood Phe control [1].

4 . References

- 1. Kuvan prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. March 2020.
- 2. Levy HL, Milanowski A, Chakrapani A, et al. Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH4) for reduction of phenylalanine concentration in patients with phenylketonuria: a phase III randomised placebo-controlled study. *Lancet*. 2007;370(9586):504-10.
- 3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. *Genet Med*. 2014 Feb;16(2):188-200.

Kynamro (mipomersen sodium)

Prior Authorization Guideline

Guideline Name	Kynamro (mipomersen sodium)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Kynamro	
Approval Length	6 Month [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia (HoFH) as confirmed by one of the following: [1-3] 1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)	

OR

1.2 Both of the following:

1.2.1 One of the following:

- Untreated LDL-C greater than 500 mg/dL
- Treated LDL-C greater than 300 mg/dL

AND

1.2.2 One of the following:

- Xanthoma before 10 years of age
- Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents

AND

2 - Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe) [A]

AND

3 - Trial and failure, contraindication, or intolerance to Repatha therapy

AND

4 - Used as adjunct to a low-fat diet and exercise regimen [1]

AND

5 - Not used in combination with Juxtapid (lomitapide)

AND

6 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

AND

7 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist [B]

Product Name: Kynamro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient continues to receive other lipid-lowering therapy</p> <p>AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction while on Kynamro therapy [C]</p> <p>AND</p> <p>3 - Patient is continuing a low-fat diet and exercise regimen</p> <p>AND</p> <p>4 - Not used in combination with Juxtapid (lomitapide)</p>	

AND

5 - Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

AND

6 - Prescribed by one of the following:

- Cardiologist
- Endocrinologist
- Lipid specialist [B]

2 . Endnotes

- A. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). [5] The effect of lomitapide on cardiovascular morbidity and mortality has not been determined. [1]
- B. Lipid specialists are physicians certified by the American Board of Clinical Lipidology (ABCL) or the Accreditation Council for Clinical Lipidology (ACCL). [6, 7] In the opinion of the ACC expert consensus writing committee, mipomersen is best administered under the care of a lipid specialist. [8]
- C. Maximal reduction of LDL-C may be seen with Kynamro therapy after approximately 6 months (based on the time to steady state seen in clinical studies). Health care providers should assess the patient's LDL-C level after 6 months to determine if the LDL-C reduction achieved with Kynamro is sufficiently robust to warrant the potential risk of liver toxicity. [1]

3 . References

1. Kynamro Prescribing Information. Genzyme Corporation. Cambridge, MA. May 2016.
2. Raal FJ, Santos RD. Homozygous familial hypercholesterolemia: current perspectives on diagnosis and treatment. *Atherosclerosis*. 2012;223:262-8.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management.

A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. *Eur Heart J*. 2014;35:2146-57.

4. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol*. 2014;63:2889-934.
5. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. *N Engl J Med*. 2015a; DOI: 10.1056/NEJMoa1410489 [Epub ahead of print].
6. American Board of Clinical Lipidology website. www.lipidboard.org. Accessed September 23, 2015.
7. Accreditation Council for Clinical Lipidology website. www.lipidspecialist.org. Accessed September 23, 2015.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol*. 2017;70:1785-1822.

Prior Authorization Guideline

Guideline Name	Lambert-Eaton Myasthenic Syndrome (LEMS) Agents - PA, NF
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Firdapse (amifampridine phosphate)
Lambert-Eaton Myasthenic Syndrome (LEMS) Indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults and pediatric patients 6 years of age and older.

2 . Criteria

Product Name: Firdapse	
Approval Length	3 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)	

AND

2 - Documentation of symptomatic LEMS that interfere with daily functions (e.g., difficulty climbing stairs, walking up steep hills)

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Firdapse

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in dynamometry, Timed 25-Foot Walk Test, Timed Up and Go Test)

Product Name: Firdapse

Approval Length	3 Month(s) [A]
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS)

AND

2 - Documentation of symptomatic LEMS that interfere with daily functions (e.g., difficulty climbing stairs, walking up steep hills)

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with a neurologist

3 . Endnotes

- A. Per clinical consultation and P&T committee recommendation, it is appropriate to check for positive clinical response earlier due to the drug's rapid onset of action. [2]

4 . References

1. Firdapse Prescribing Information. Catalyst Pharmaceuticals, Inc. Coral Gables, FL. September 2022.
2. Per clinical consult with neurologist. January 18, 2019.

Prior Authorization Guideline

Guideline Name	Lenvima (lenvatinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Lenvima (lenvatinib)
<p>Differentiated Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC).</p> <p>Renal Cell Carcinoma 1) Indicated for use in combination with everolimus for the treatment of adult patients with advanced renal cell carcinoma (RCC) following one prior anti-angiogenic therapy. 2) Indicated as first-line treatment of adult patients with advanced RCC in combination with pembrolizumab.</p> <p>Hepatocellular Carcinoma Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC).</p> <p>Endometrial Carcinoma In combination with pembrolizumab, is indicated for the treatment of patients with advanced endometrial carcinoma (EC) that is mismatch repair proficient (pMMR), as determined by an FDA-approved test, or not microsatellite instability-high (MSI-H), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation</p>

2 . Criteria

Product Name: Lenvima	
Diagnosis	Differentiated thyroid cancer (DTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of differentiated thyroid cancer (DTC) [A]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <ul style="list-style-type: none"> • Locally recurrent disease • Metastatic disease <p style="text-align: center;">AND</p> <p>3 - One of the following: [2]</p> <ul style="list-style-type: none"> • Patient has symptomatic disease • Patient has progressive disease <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Lenvima	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [4]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - One of the following:

3.1 Both of the following*: [4]

- Treatment follows one prior anti-angiogenic therapy [e.g., Inlyta (axitinib), Votrient (pazopanib), Nexavar (sorafenib), Sutent (sunitinib)]
- Used in combination with Afinitor (everolimus) for clear cell renal cell carcinoma [B]

OR

3.2 Both of the following*: [4]

- Used as first-line treatment for clear cell renal cell carcinoma
- Used in combination with Keytruda (pembrolizumab)

OR

3.3 One of the following:

3.3.1 Both of the following: [4]

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR	
3.3.2 For continuation of prior therapy	
AND	
4 - Prescribed by or in consultation with an oncologist	
Notes	*Criterion is part of FDA-approved label.

Product Name: Lenvima	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hepatocellular carcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Oncologist • Hepatologist • Gastroenterologist 	

Product Name: Lenvima	
Diagnosis	Endometrial Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

AND

2 - Patient has disease progression following systemic therapy

AND

3 - Used in combination with Keytruda (pembrolizumab) therapy

AND

4 - Patient is not a candidate for curative surgery or radiation

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Lenvima	
Diagnosis	All indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Differentiated thyroid carcinoma includes papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and poorly differentiated carcinoma. [2]
- B. NCCN recognizes use for subsequent therapy in combination with everolimus for relapse or for surgically unresectable stage IV disease with predominant clear cell histology that progressed on prior antiangiogenic therapy. [2]

4 . References

1. Lenvima Prescribing Information. Eisai Inc. Nutley, NJ. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 2, 2019.
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. v3.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf. Accessed September 5, 2018.
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Kidney Cancer. V1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed July 20, 2022.

Litfulo (ritlecinib)

Prior Authorization Guideline

Guideline Name	Litfulo (ritlecinib)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Litfulo (ritlecinib)
Alopecia Areata (AA) Indicated for the treatment of adult and adolescent patients 12 years and older with severe alopecia areata. Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

2 . Criteria

Product Name: Litfulo	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1,2]

AND

3 - Other causes of hair loss have been ruled out (e.g., other types of alopecia, scalp disease, active systemic disease) [2]

AND

4 - Patient is 12 years of age or older

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants

Product Name: Litfulo	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy

AND

2 - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants

3 . References

1. Litfulo Prescribing Information. Pfizer. New York, NY. June 2023.
2. King B, Zhang X, Harcha WG, et al. Efficacy and safety of ritlecitinib in adults and adolescents with alopecia areata: a randomised, double-blind, multicentre, phase 2b-3 trial. *Lancet*. 2023;401(10387):1518-1529.

Prior Authorization Guideline

Guideline Name	Livmarli (maralixibat) - PA, NF
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Livmarli (maralixibat)
Alagille syndrome Indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older.

2 . Criteria

Product Name: Livmarli	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Both of the following:	

1.1 Diagnosis of Alagille Syndrome (ALGS)

AND

1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [A, 2, 6]

AND

2 - Documentation of ONE of the following: [4]

- Total serum bile acid > 3x the upper limit of normal (ULN)
- Conjugated bilirubin > 1 mg/dL
- Fat soluble vitamin deficiency otherwise unexplainable
- Gammaglutamyl transpeptidase (GGT) > 3x ULN

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus [4]

AND

4 - Patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [B, 2, 7]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist

Product Name: Livmarli	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score)</p>	

Product Name: Livmarli	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Diagnosis of Alagille Syndrome (ALGS)</p> <p style="text-align: center;">AND</p> <p>1.2 Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene [A, 2, 6]</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of ONE of the following: [4]</p> <ul style="list-style-type: none"> • Total serum bile acid > 3x the upper limit of normal (ULN) • Conjugated bilirubin > 1 mg/dL • Fat soluble vitamin deficiency otherwise unexplainable • Gammaglutamyl transpeptidase (GGT) > 3x ULN 	

AND

3 - Patient is experiencing moderate to severe cholestatic pruritus [4]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has had an inadequate response to at least two of the following treatments used for the relief of pruritus: [B, 2, 7]

- Ursodeoxycholic acid (e.g., Ursodiol)
- Antihistamines (e.g., diphenhydramine, hydroxyzine)
- Rifampin
- Bile acid sequestrants (e.g., Questran, Colestid, Welchol)

AND

5 - Patient is 3 months of age or older

AND

6 - Prescribed by or in consultation with a hepatologist

3 . Endnotes

- A. Alagille Syndrome is an autosomal dominant disease with variable expressivity, caused by heterozygous mutations in either JAG1 or NOTCH2. The vast majority of cases are due to JAG1 mutations accounting for 94%, and NOTCH2 mutations in additional 2–4%. [2]
- B. The management of pruritus in ALGS is challenging, and a variety of therapies are often used. These include antihistamines, rifampin, ursodeoxycholic acid, cholestyramine, naltrexone, and sertraline. Clinical experience suggests that these drugs have variable efficacy in reducing pruritus; however, no prospective clinical trials has quantified the effect of any of these therapies, either alone or in combination. [7]

4 . References

1. Livmarli Prescribing Information. Mirum Pharmaceuticals, Inc. Foster City, CA. March 2023.
2. Ayoub MD, Kamath BM. Alagille Syndrome: Diagnostic Challenges and Advances in Management. *Diagnostics (Basel)*. 2020;10(11):907. Published 2020 Nov 6. doi:10.3390/diagnostics10110907
3. Saleh M, Kamath BM, Chitayat D. Alagille syndrome: clinical perspectives. *Appl Clin Genet*. 2016;9:75-82. Published 2016 Jun 30. doi:10.2147/TACG.S86420
4. ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/study/NCT02160782> Accessed October 18, 2021.
5. Emerick KM, Elias MS, Melin-Aldana H, et al. Bile composition in Alagille Syndrome and PFIC patients having Partial External Biliary Diversion. *BMC Gastroenterol*. 2008;8:47. Published 2008 Oct 20. doi:10.1186/1471-230X-8-47
6. Diaz-Frias J, Kondamudi NP. Alagille Syndrome. [Updated 2021 Jun 26]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK507827/>
7. Shneider BL, Spino C, Kamath BM, et al. Placebo-Controlled Randomized Trial of an Intestinal Bile Salt Transport Inhibitor for Pruritus in Alagille Syndrome. *Hepatol Commun*. 2018;2(10):1184-1198.

Livtency (maribavir)

Prior Authorization Guideline

Guideline Name	Livtency (maribavir)
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Guideline Note:

Effective Date:	6/15/2022
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1 . Indications

Drug Name: Livtency (maribavir)
Cytomegalovirus (CMV) infection/disease Indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus (CMV) infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

2 . Criteria

Product Name: Livtency	
Diagnosis	CMV infection/disease
Approval Length	8 Week(s) [1]
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cytomegalovirus (CMV) infection/disease as confirmed by one of the following methods: [2, 3]

- quantitative polymerase chain reaction (qPCR)
- CMV pp65 antigenemia

AND

2 - Patient is a recipient of one of the following:

- Hematopoietic stem cell transplant
- Solid organ transplant

AND

3 - Trial and failure of a minimum 2 weeks duration, contraindication, or intolerance to one of the following therapies at an appropriately indicated dose:

- Intravenous (IV) ganciclovir
- Oral valganciclovir
- IV foscarnet
- IV cidofovir

AND

4 - Patient is 12 years of age or older

AND

5 - Patient weighs greater than or equal to 35kg

AND

6 - Prescribed by or in consultation with a provider who specializes in one of the following areas:

- Transplant

- Infectious Disease

3 . References

1. Livtency Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. November 2021.
2. Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients— Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. *Clinical Transplantation*. 2019;33(9).
3. ClinicalTrials.gov [Internet]. U.S. National Library of Medicine. Identifier NCT02931539. Efficacy and Safety Study of Maribavir Treatment Compared to Investigator-assigned Treatment in Transplant Recipients With Cytomegalovirus (CMV) Infections That Are Refractory or Resistant to Treatment With Ganciclovir, Valganciclovir, Foscarnet, or Cidofovir; October 13, 2016. Available from: <https://clinicaltrials.gov/ct2/show/NCT02931539>.

Prior Authorization Guideline

Guideline Name	Lonsurf (trifluridine and tipiracil)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Lonsurf (trifluridine and tipiracil)
Metastatic Colorectal Cancer Indicated for the treatment of adult patients with metastatic colorectal cancer (mCRC) as a single agent or in combination with bevacizumab who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an antiEGFR therapy.
Metastatic Gastric Cancer Indicated for the treatment of adult patients with metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/neu-targeted therapy.

2 . Criteria

Product Name: Lonsurf	
Diagnosis	Metastatic Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic colorectal cancer (mCRC)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Used as a single agent</p> <p style="text-align: center;">OR</p> <p>2.2 Used in combination with bevacizumab</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, intolerance or contraindication to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, intolerance or contraindication to an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])</p> <p style="text-align: center;">AND</p> <p>5 - One of the following:</p> <p>5.1 Patient has RAS mutant tumors</p> <p style="text-align: center;">OR</p>	

5.2 Both of the following:

5.2.1 Patient has RAS wild-type tumors

AND

5.2.2 Trial and failure, intolerance or contraindication to an anti-EGFR therapy (e.g., Vectibix [panitumumab], Erbitux [cetuximab])

Product Name: Lonsurf	
Diagnosis	Metastatic Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Diagnosis of Metastatic Gastric Cancer	
OR	

1.2 Diagnosis of gastroesophageal junction adenocarcinoma

AND

2 - Trial and failure, contraindication or intolerance to two of the following:

- Fluoropyrimidine-based chemotherapy
- Platinum-based chemotherapy
- Taxane or irinotecan-based chemotherapy
- HER2/neu-targeted therapy (if appropriate)

Product Name: Lonsurf	
Diagnosis	Gastric/Gastroesophageal Junction Adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Lonsurf Prescribing Information. Taiho Oncology, Inc. Princeton, NJ. January 2020.
2. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2019. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 19, 2019.

Lorbrena (lorlatinib)

Prior Authorization Guideline

Guideline Name	Lorbrena (lorlatinib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Lorbrena (lorlatinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name: Lorbrena	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer (NSCLC)	

AND

2 - One of the following:

2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

- Alecensa (alectinib)
- Alunbrig (brugatinib)

OR

2.2 For continuation of prior therapy

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Lorbrena	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while therapy	

3 . References

1. Lorbrena Prescribing Information. Pfizer Labs. New York, NY. March 2021.

Lumakras (sotorasib)

Prior Authorization Guideline

Guideline Name	Lumakras (sotorasib)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Lumakras (sotorasib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Lumakras	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy)

Product Name: Lumakras

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lumakras [package insert]. Thousand Oaks, CA: Amgen, Inc; May 2021.
2. Skoulidis F, Li BT, Dy GK, et al. Sotorasib for lung cancers with KRAS p.G12C mutation. N Engl J Med 2021;384:2371-2381.

Lunsumio (mosunetuzumab-axgb)

Prior Authorization Guideline

Guideline Name	Lunsumio (mosunetuzumab-axgb)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Lunsumio (mosunetuzumab-axgb)
Follicular Lymphoma Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Lunsumio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of follicular lymphoma

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has had two or more lines of systemic therapy (e.g., chemotherapy)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Lunsumio

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Lunsumio prescribing information. Genentech, Inc. South San Francisco, CA. December 2022.

Lupkynis (voclosporin)

Prior Authorization Guideline

Guideline Name	Lupkynis (voclosporin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Lupkynis (voclosporin)
Lupus Nephritis Indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active lupus nephritis (LN). Limitations of Use: Safety and efficacy of Lupkynis have not been established in combination with cyclophosphamide. Use of Lupkynis is not recommended in this situation.

2 . Criteria

Product Name: Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of active lupus nephritis

AND

2 - Used in combination with immunosuppressive therapy (e.g., mycophenolate mofetil, methylprednisolone)

AND

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Rheumatologist

Product Name: Lupkynis	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Lupkynis Prescribing Information. Aurinia Pharma U.S., Inc. Rockville, MD. January 2021.

Prior Authorization Guideline

Guideline Name	Lynparza (olaparib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Lynparza (olaparib)
<p>First-line maintenance treatment of BRCA-mutated advanced ovarian cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCA or sBRCA) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.</p> <p>Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer Indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.</p> <p>First-line maintenance treatment of HRD-positive advanced ovarian cancer in combination with bevacizumab Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.</p> <p>Germline BRCA-mutated HER2-negative high risk early breast cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCA-</p>

mutated, HER2-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Germline BRCA-mutated HER2-negative metastatic breast cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious gBRCA-mutated, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

First-line maintenance treatment of germline BRCA-mutated metastatic pancreatic adenocarcinoma Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

HRR gene-mutated metastatic castration-resistant prostate cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) Indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

2 . Criteria

Product Name: Lynparza	
Diagnosis	Epithelial ovarian, Fallopian tube, or Primary peritoneal cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of one of the following:

- Epithelial ovarian cancer
- Fallopian tube cancer
- Primary peritoneal cancer

Product Name: Lynparza

Diagnosis	Breast cancer
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of breast cancer

Product Name: Lynparza

Diagnosis	Pancreatic adenocarcinoma
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis pancreatic adenocarcinoma

Product Name: Lynparza

Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)

AND

2 - Presence of a deleterious or suspected deleterious BRCA-mutation or homologous recombination repair (HRR) gene mutation as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - For BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), Lynparza is used in combination with abiraterone and one of the following:

- prednisone
- prednisolone

Product Name: Lynparza	
Diagnosis	All Indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Lynparza Tablets prescribing information. AstraZeneca Pharmaceuticals LP, Inc. Wilmington, DE. May 2023.

2. Lynparza FDA Medical Review.
http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/206162Orig1s000MedR.pdf.
Accessed on June 12, 2015.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at
http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed
March 9, 2021.
4. Robson M, Im SA, Senkus E, et al. Olaparib for Metastatic Breast Cancer in Patients
with a Germline BRCA Mutation. N Engl J Med. 2017 Aug 10;377(6):523-533
5. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion
Diagnostic Devices (In Vitro and Imaging Tools). Available at
[https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/
ucm301431.htm](https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm) Accessed 3/7/2018

Lytgobi (futibatinib)

Prior Authorization Guideline

Guideline Name	Lytgobi (futibatinib)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Lytgobi (futibatinib)
Cholangiocarcinoma Indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Lytgobi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of intrahepatic cholangiocarcinoma

AND

2 - Disease is one of the following:

- Unresectable
- Locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements [A]

AND

4 - Patient has been previously treated (e.g., chemotherapy)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Oncologist

Product Name: Lytgobi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. An FDA-approved test for detection of FGFR2 gene fusions or other rearrangements in patients with unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma for selecting patients for treatment with LYTGObI is not available. The presence of FGFR2 fusions or other rearrangements was determined using next generation sequencing (NGS) testing. [1]

4 . References

1. Lytgobi Prescribing Information. Taiho Oncology, Inc. Princeton, NJ. September 2022.

Prior Authorization Guideline

Guideline Name	Managed Administrative Biosimilars Policy - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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Note:

This guideline applies to non-formulary biosimilars. For the following Tier 2 products: Humira, Cyltezo, Hadlima, and Brand Adalimumab-adbm, refer to the "Adalimumab" guideline for review.

1 . Indications

Drug Name: Amjevita (adalimumab-atto)
Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).
Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Can be used alone or in combination with methotrexate.
Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Can be used alone or in combination with non-biologic DMARDs.
Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when

other systemic therapies are medically less appropriate. Should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Uveitis (UV) Indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.

Drug Name: Abrilada (adalimumab-afzb), Hulio (adalimumab-fkjp), Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh)

Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Can be used alone or in combination with methotrexate.

Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Hidradenitis Suppurativa (HS) Indicated for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Off Label Uses: Uveitis (UV) Adalimumab may be used for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

Drug Name: Idacio (adalimumab-aacf)

Rheumatoid arthritis (RA) Indicated for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis. Can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs).

Polyarticular Juvenile idiopathic arthritis (PJIA) Indicated for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. Can be used alone or in combination with methotrexate.

Psoriatic arthritis (PsA) Indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis. Can be used alone or in combination with non-biologic DMARDs.

Plaque psoriasis (PsO) Indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. Should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Ankylosing spondylitis (AS) Indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Crohn's disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.

Ulcerative Colitis (UC) Indicated for the treatment of moderately to severely active ulcerative colitis in adult patients. Limitations of use: The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF-blockers.

Off Label Uses: Hidradenitis Suppurativa (HS) Adalimumab may be used for the treatment of moderate to severe hidradenitis suppurativa in adult patients.

Uveitis (UV) Adalimumab may be used for the treatment of non-infectious intermediate, posterior and panuveitis in adults and pediatric patients 2 years of age and older.

2 . Criteria

Product Name: Abrilada*, Amjevita (Tier 3, Non-Preferred or NF)*, Hulio*, Brand Adalimumab-fkjp*, Idacio*, Yuflyma*, Yusimry*

Approval Length 12 month(s)

Guideline Type Prior Authorization, Non Formulary

Approval Criteria

1 - Patient has one of the following diagnoses:

- Rheumatoid arthritis
- Polyarticular juvenile idiopathic arthritis
- Psoriatic arthritis
- Plaque psoriasis
- Ankylosing spondylitis
- Crohn’s disease
- Ulcerative colitis
- Hidradenitis suppurativa
- Uveitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 6-month trial of TWO of the following:

- Humira (adalimumab)
- Cyltezo (adalimumab-adbm) or Brand adalimumab-adbm
- Hadlima (adalimumab-bwwd)

AND

3 - Submission of medical records documenting why the covered products have not been effective

Notes

Abrilada, Amjevita, Hulio, Brand Adalimumab-fkjp, Idacio, Yuflyma, and Yusimry are non-formulary. Plan covers the following Tier 2 products: Humira, Cyltezo, Brand Adalimumab-adbm, and Hadlima. See Background section for NDCs.

*If patient meets criteria above, please approve at NDC list “OOADALIMUM”.

3 . Background

Benefit/Coverage/Program Information		
Preferred and Nonpreferred Adalimumab NDCs		
Preferred Products – TIER 2	NDC	
HUMIRA PEN INJ 40MG/0.8	00074433902	
HUMIRA PEN INJ CD/UC/HS	00074433906	
HUMIRA PEN INJ PS/UV	00074433907	
HUMIRA PEN INJ 40/0.4ML	00074055402	
HUMIRA PEN INJ 40/0.4ML	00074055471	
HUMIRA PEN INJ 80/0.8ML	00074012402	
HUMIRA PEN KIT CD/UC/HS	00074012403	
HUMIRA PEN KIT PED UC	00074012404	
HUMIRA PEN KIT CD/UC/HS	00074012474	
HUMIRA PEN KIT PS/UV	00074153903	
HUMIRA INJ 10/0.1ML	00074081702	
HUMIRA INJ 20/0.2ML	00074061602	
HUMIRA KIT 40MG/0.8	00074379902	
HUMIRA INJ 40/0.4ML	00074024302	
HUMIRA PEDIA INJ CROHNS	00074254003	
HUMIRA PEDIA INJ CROHNS	00074006702	
ADALIMU-ADBМ KIT 40/0.8ML	00597054522	
ADALIMU-ADBМ KIT 10/0.2ML	00597058589	
ADALIMU-ADBМ KIT 20/0.4ML	00597055580	
ADALIMU-ADBМ KIT 40/0.8ML	00597054544	
ADALIMU-ADBМ KIT 40/0.8ML	00597054566	
ADALIMU-ADBМ KIT 40/0.8ML	00597059520	
CYLTEZO INJ 10/0.2ML	00597040089	

CYLTEZO	INJ 20/0.4ML	00597040580
CYLTEZO	INJ 40/0.8ML	00597037597
CYLTEZO	INJ 40/0.8ML	00597037082
CYLTEZO	INJ CROHNS	00597037516
CYLTEZO	INJ PSORIASI	00597037523
HADLIMA PUSH INJ 40/0.4ML		78206018701
HADLIMA PUSH INJ 40/0.8ML		78206018401
HADLIMA	INJ 40/0.4ML	78206018601
HADLIMA	INJ 40/0.8ML	78206018301

Nonpreferred Products – TIER 3	NDC
ADALIMU-FKJP KIT 20/0.4ML	49502041702
ADALIMU-FKJP KIT 20/0.4ML	49502041706
ADALIMU-FKJP KIT 40/0.8ML	49502041602
ADALIMU-FKJP KIT 40/0.8ML	49502041606
ADALIMU-FKJP KIT 40/0.8ML	49502041802
ADALIMU-FKJP KIT 40/0.8ML	49502041806
AMJEVITA INJ 10/0.2ML	55513041301
AMJEVITA INJ 20/0.4ML	55513041101
AMJEVITA INJ 40/0.8ML	55513040001
AMJEVITA INJ 40/0.8ML	55513040002
AMJEVITA INJ 40/0.8ML	72511040001
AMJEVITA INJ 40/0.8ML	72511040002
AMJEVITA INJ 40/0.8ML	55513041001
HULIO INJ 40/0.8ML	49502038002
HULIO INJ 40/0.8ML	49502038202
HULIO KIT 20/0.4ML	49502038102
ADALIMU-ADAZ INJ 40/0.4ML	61314032720
ADALIMU-ADAZ INJ 40/0.4ML	61314032764

HYRIMOZ INJ 10/0.1ML	61314050964
HYRIMOZ INJ 20/0.2ML	61314047664
HYRIMOZ INJ 40/0.4ML	61314047320
HYRIMOZ INJ 40/0.4ML	61314047364
HYRIMOZ INJ 80/0.8ML	61314045420
HYRIMOZ-CROH INJ UC SP	61314045436
HYRIMOZ-PED INJ CROHNS	61314045468
HYRIMOZ-PED INJ CROHNS	61314053164
HYRIMOZ-PLAQ INJ PSORIASI	61314051736
IDACIO INJ 40/0.8ML	65219055408
IDACIO INJ 40/0.8ML	65219055618
IDACIO CROHN INJ DISEASE	65219055438
IDACIO PLAQU INJ PSORIASI	65219055428
YUFLYMA 1PEN KIT 40/0.4ML	72606003009
YUFLYMA 2PEN KIT 40/0.4ML	72606003010
YUFLYMA 2SYR KIT 40/0.4ML	72606003006
YUSIMRY INJ 40/0.8ML	70114022002

4 . References

1. Amjevita Prescribing Information. Amgen Inc. Thousand Oaks, CA. July 2023.
2. Abrilada Prescribing Information. Pfizer Inc. New York, NY. June 2023.
3. Hulio Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. March 2023.
4. Idacio Prescribing Information. Fresenius Kabi. Lake Zurich, IL. December 2022.
5. Yuflyma Prescribing Information. Celltrion Inc. Jersey City, NJ. May 2023.
6. Yusimry Prescribing Information. Coherus BioSciences Inc. Redwood City, CA. March 2023.
- 7.

Mavyret (glecaprevir/pibrentasvir)

Prior Authorization Guideline

Guideline Name	Mavyret (glecaprevir/pibrentasvir)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Mavyret (glecaprevir/pibrentasvir)
Chronic Hepatitis C Virus (HCV) Indicated for the treatment of adult and pediatric patients 3 years and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

2 . Criteria

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Naïve; without Decompensated Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is treatment-naive

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS3/4A Protease Inhibitor); without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]

AND

3 - Patient has had no previous treatment experience with a treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1; Treatment-Experienced (Prior failure to an NS5A Inhibitor); without Decompensated Cirrhosis
Approval Length	16 Week(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])</p> <p style="text-align: center;">AND</p> <p>3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)]</p> <p style="text-align: center;">AND</p> <p>4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious disease specialist • HIV specialist certified through the American Academy of HIV Medicine <p style="text-align: center;">AND</p> <p>6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]</p>	

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 3</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)</p> <p style="text-align: center;">AND</p> <p>3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])</p> <p style="text-align: center;">AND</p> <p>4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious disease specialist • HIV specialist certified through the American Academy of HIV Medicine <p style="text-align: center;">AND</p>	

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen</p> <p style="text-align: center;">AND</p> <p>3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])</p> <p style="text-align: center;">AND</p> <p>4 - Patient is without cirrhosis</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Hepatologist• Gastroenterologist• Infectious disease specialist	

- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6</p> <p>AND</p> <p>2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen</p> <p>AND</p> <p>3 - Patient has had no previous treatment experience with a treatment regimen that included a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (e.g., Daklinza [daclatasvir])</p> <p>AND</p> <p>4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)</p> <p>AND</p>	

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6</p> <p>AND</p> <p>2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)</p> <p>AND</p> <p>3 - Patient has had no previous treatment experience with an HCV NS3/4A protease inhibitor inclusive combination direct acting antiviral regimen (e.g., Zepatier [elbasvir/grazoprevir])</p> <p>AND</p>	

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6	
AND	
2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]	
AND	
3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]	

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6	
AND	
2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [2]	

AND

3 - Used in combination with Sovaldi (sofosbuvir) and ribavirin [2]

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; HCV-Uninfected Recipients of a Liver Transplant from HCV-Viremic Donors; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Both of the following [2]:	
<ul style="list-style-type: none">• Patient was not infected with HCV prior to receiving a liver transplant	

- Patient received a liver transplant from a donor with a diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Mavyret (glecaprevir/pibrentasvir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6 Post-Liver or Kidney Transplant; without Decompensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6</p> <p>AND</p> <p>2 - Patient has had a liver or kidney transplant [2]</p>	

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Mavyret Prescribing Information. Abbvie Inc. North Chicago, IL. September 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. October 2022. <http://www.hcvguidelines.org/full-report-view>. Accessed May 14, 2023.

Prior Authorization Guideline

Guideline Name	Mekinist (trametinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Mekinist (trametinib)
<p>BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of BRAF-inhibitor treatment-naïve patients or in combination with dabrafenib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test.</p> <p>BRAF V600E mutation-positive metastatic non-small cell lung cancer Indicated in combination with dabrafenib for the treatment of patients with metastatic non-small cell lung cancer with BRAF V600E mutation as detected by an FDA-approved test.</p> <p>Adjuvant treatment for BRAF V600E or V600K mutation-positive melanoma Indicated for adjuvant treatment in combination with dabrafenib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node (s), following complete resection.</p> <p>Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional options.</p> <p>BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with dabrafenib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.</p>

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with dabrafenib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

2 . Criteria

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses: [2]</p> <ul style="list-style-type: none"> • Unresectable melanoma • Metastatic melanoma <p style="text-align: center;">AND</p> <p>2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]</p>	

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Mekinist

Diagnosis	Non-small cell lung cancer
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist

Diagnosis	Non-small cell lung cancer
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Mekinist	
Diagnosis	Adjuvant treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of melanoma</p> <p style="text-align: center;">AND</p> <p>2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>3 - Involvement of lymph nodes following complete resection [2]</p> <p style="text-align: center;">AND</p> <p>4 - Used as adjunctive therapy</p> <p style="text-align: center;">AND</p> <p>5 - Medication is used in combination with Tafinlar (dabrafenib)</p>	

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [4]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Mekinist	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of solid tumors</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 6 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Disease is one of the following:</p> <ul style="list-style-type: none"> • unresectable • metastatic <p style="text-align: center;">AND</p> <p>4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options</p> <p style="text-align: center;">AND</p> <p>5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>6 - Medication is used in combination with Tafinlar (dabrafenib)</p>	

Product Name: Mekinist

Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of low-grade glioma</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient requires systemic therapy</p> <p style="text-align: center;">AND</p> <p>4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

AND

5 - Medication is used in combination with Tafinlar (dabrafenib)

Product Name: Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. The recommended dosage of MEKINIST is 2 mg orally taken once daily in combination with dabrafenib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Mekinist Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Melanoma v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 15, 2022.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 15, 2022.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 15, 2021.

Mektovi (binimetinib)

Prior Authorization Guideline

Guideline Name	Mektovi (binimetinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Mektovi (binimetinib)
BRAF V600E or V600K unresectable or metastatic melanoma Indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test.

2 . Criteria

Product Name: Mektovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following diagnoses:	

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Used in combination with encorafenib

AND

4 - One of the following:

4.1 Trial and failure, contraindication or intolerance to one of the following:

- Cotellic
- Mekinist

OR

4.2 For continuation of prior therapy

Product Name: Mektovi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Mektovi Prescribing Information. Array Biopharma Inc. Boulder, CO. October 2020.
2. National Comprehensive Cancer Network (NCCN). Clinical practice guidelines in oncology: Melanoma: Cutaneous v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed May 23, 2022.

Prior Authorization Guideline

Guideline Name	Methotrexate Auto-injectors
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Otrexup (methotrexate injection)
<p>Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).</p> <p>Polyarticular Juvenile Idiopathic Arthritis Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).</p> <p>Psoriasis Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis “flare” is not due to an undiagnosed concomitant disease affecting immune responses.</p> <p>Limitation of Use Not indicated for the treatment of neoplastic diseases.</p>
Drug Name: Rasuvo (methotrexate injection)
<p>Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-</p>

inflammatory agents (NSAIDs).

Polyarticular Juvenile Idiopathic Arthritis Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

Psoriasis Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses.

Limitation of Use Not indicated for the treatment of neoplastic diseases.

Drug Name: Reditrex (methotrexate injection)

Rheumatoid Arthritis Indicated in the management of selected adults with severe, active rheumatoid arthritis (RA) (ACR criteria) who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

Polyarticular Juvenile Idiopathic Arthritis Indicated in the management of children with active polyarticular juvenile idiopathic arthritis (pJIA), who have had an insufficient therapeutic response to, or are intolerant of, an adequate trial of first-line therapy including full dose non-steroidal anti-inflammatory agents (NSAIDs).

Psoriasis Indicated in adults for the symptomatic control of severe, recalcitrant, disabling psoriasis that is not adequately responsive to other forms of therapy, but only when the diagnosis has been established, as by biopsy and/or after dermatologic consultation. It is important to ensure that a psoriasis "flare" is not due to an undiagnosed concomitant disease affecting immune responses.

Limitation of Use Not indicated for the treatment of neoplastic diseases.

2 . Criteria

Product Name: Rasuvo, Reditrex	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of severe, active rheumatoid arthritis

AND

1.1.2 Prescribed by or in consultation with a rheumatologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

1.2.2 Prescribed by or in consultation with a rheumatologist

OR

1.3 Both of the following:

1.3.1 Diagnosis of severe psoriasis

AND

1.3.2 Prescribed by or in consultation with a dermatologist

AND

2 - Trial and failure or intolerance to oral methotrexate

Product Name: Otrexup

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of severe, active rheumatoid arthritis

AND

1.1.2 Prescribed by or in consultation with a rheumatologist

OR

1.2 Both of the following:

1.2.1 Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

1.2.2 Prescribed by or in consultation with a rheumatologist

OR

1.3 Both of the following:

1.3.1 Diagnosis of severe psoriasis

AND

1.3.2 Prescribed by or in consultation with a dermatologist

AND

2 - Trial and failure or intolerance to both of the following:

- Oral methotrexate
- Rasuvo or Reditrex

Product Name: Otrexup, Rasuvo, Reditrex	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . References

1. Otrexup Prescribing Information. Antares Pharma, Inc, Ewing, NJ. December 2019.
2. Rasuvo Prescribing Information, Medac Pharma, Inc. Chicago, IL. March 2018.
3. Reditrex Prescribing Information. Cumberland Pharmaceuticals Inc., Nashville, TN. November 2019.

Miebo (perfluorohexyloctane ophthalmic solution)

Prior Authorization Guideline

Guideline Name	Miebo (perfluorohexyloctane ophthalmic solution)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Miebo (perfluorohexyloctane ophthalmic solution)
Dry Eye Disease Indicated for the treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name: Miebo	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of dry eye disease confirmed by ONE of the following diagnostic tests: [A, 2-4]	
<ul style="list-style-type: none">• Schirmer test	

- Ocular surface dye staining (e.g., rose bengal, fluorescein, lissamine green)
- Tear function index/fluorescein clearance test
- Tear break up time
- Tear film osmolarity
- Slit lamp lid evaluation
- Lacrimal gland function

AND

2 - Trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) [B, 2-4]

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- Restasis (cyclosporine 0.05%)
- Xiidra (lifitegrast)

AND

4 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name: Miebo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)	

3 . Endnotes

- A. Traditional diagnostic tests include the Schirmer test, ocular surface dye staining, tear function index/fluorescein clearance test, tear break up time, tear film osmolarity, slit lamp evaluation of lid [2-4]
- B. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (e.g., emulsions, gels, ointments). Anti-inflammatory therapies (e.g., topical cyclosporine, corticosteroids), systemic omega-3 fatty acid supplements, punctal plugs, and eyeglass side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management [2-4]

4 . References

1. Miebo Prescribing Information. Bausch & Lomb Americas Inc. Bridgewater, NJ. May 2023.
2. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. October 2018. Available at file:///C:/Users/kdekhtaw/OneDrive%20-%20UHG/Homedir/2020%20CLIENT%20LISTS/UTILIZATION%20MANAGEMENT/M/MI EBO/Dry%20Eye%20Syndrome%20Preferred%20Practice%20Pattern%202018.pdf. Accessed July 11, 2023.
3. Wood, S., Mian, S. Diagnostic Tools for Dry Eye Disease. Available at https://www.touchophthalmology.com/wp-content/uploads/sites/16/2017/01/Diagnostic-Tools-for-Dry-Eye-Disease_1.pdf. Accessed Nov 9, 2021.
4. Zeev, M., Miller, D, et al. Diagnosis of dry eye disease and emerging technologies. Clin Ophthalmol 2014;8:581-590. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3964175/#b16-opth-8-581>. Accessed November 9, 2021.
5. Tauber, J., Berdy, G., et al. NOV03 for Dry Eye Disease Associated with Meibomian Gland Dysfunction: Results of the Randomized Phase 3 GOBI Study. American Academy of Ophthalmology. Dec 2022: 516-524. Available at:[https://www.aajournal.org/article/S0161-6420\(22\)01016-8/pdf#:~:text=NOV03%2C%20a%20novel%2C%20nonaqueous%2C%20single-entity%2C%20preservative-%20free%2C%20ophthalmic,glands%20through%2024%20hours%2C%20with%20minimal%20systemic%20exposure.26](https://www.aajournal.org/article/S0161-6420(22)01016-8/pdf#:~:text=NOV03%2C%20a%20novel%2C%20nonaqueous%2C%20single-entity%2C%20preservative-%20free%2C%20ophthalmic,glands%20through%2024%20hours%2C%20with%20minimal%20systemic%20exposure.26). Accessed July 11, 2023.
6. Sheppard,J., Kurata, F., et al. NOV03 for Signs and Symptoms of Dry Eye Disease Associated With Meibomian Gland Dysfunction: The Randomized Phase 3 MOJAVE Study. American Journal of Ophthalmology. Mar 2023: 265-274. Available at: <https://www.ajo.com/action/showPdf?pii=S0002-9394%2823%2900098-3>. Accessed July 11, 2023.

Prior Authorization Guideline

Guideline Name	Migraine Quantity Limit
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzetra (sumatriptan), Relpax (eletriptan), Tosymra (sumatriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.

Drug Name: Axert (almotriptan)

Migraine Headaches Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and

effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)

Migraine headaches Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Drug Name: Migranal (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Drug Name: Zomig (zolmitriptan) nasal spray

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection

Migraine Headache Indicated for the acute treatment of migraine headaches with or without aura.

Cluster Headaches Indicated for acute treatment of cluster headache episodes.

Drug Name: Imitrex (sumatriptan) injection

Migraine Headache Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks.

Cluster Headaches Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.

Drug Name: Trudhesa (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine

Drug Name: Nurtec ODT (rimegepant sulfate)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.

Drug Name: Ubrelvy (ubrogepant)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Onzetra, Brand Relpax, Generic eletriptan, Sumavel DosePro, Tosymra, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, Generic zolmitriptan, or Brand Zolmitriptan nasal spray

Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Patient is experiencing 2 or more headaches per month [10-12]

AND

3 - Patient will not be treating 15 or more headache days per month

AND

4 - Currently receiving prophylactic therapy with at least one of the following: [A, 10, 25]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- An angiotensin receptor blocker (i.e., Atacand [candesartan])
- An angiotensin-converting enzyme (ACE) inhibitor (i.e., lisinopril)

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Pain specialist
- Headache specialist [B]

AND

6 - Not used in combination with another triptan-containing product

AND

7 - One of the following: [C]

7.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

7.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Product Name: Brand D.H.E. 45, Generic dihydroergotamine mesylate injection, Brand Migranal, Generic dihydroergotamine mesylate nasal spray, Nurtec ODT, Trudhesa, or Ubrelvy

Approval Length	12 month(s)
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Guideline Type	Quantity Limit
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Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following: [C]

2.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer's prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3 . Endnotes

- A. The American Academy of Neurology and American Headache Society support the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [10, 25]
- B. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [24]
- C. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4 . References

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2. Almotriptan Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. May 2017.
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4. Imitrex Tablets Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2020.
5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
6. Imitrex Injection Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2021.
7. Maxalt/Maxalt MLT Prescribing Information. Organon LLC. Jersey City, NJ. June 2021.
8. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
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14. Treximet Prescribing Information. Currax Pharmaceuticals LLC. Brentwood, TN. October 2021.
15. Zomig/Zomig ZMT Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
16. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
17. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
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19. Zembrace SymTouch Prescribing Information. Promius Pharma, LLC. Princeton, NJ. June 2019.
20. Tosymra Prescribing Information. Promius Pharma, LLC. Princeton, NJ. January 2019.
21. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.
22. Nurtec ODT Prescribing Information. Biohaven Pharmaceuticals, Inc. New Haven, CT. April 2022.
23. Ubrelvy Prescribing Information. Allergan USA, Inc. Madison, NJ. March 2021.
24. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed February 13, 2023.
25. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. *Headache.* 2021 Jul;61(7):1021-1039.

Prior Authorization Guideline

Guideline Name	Mitoxantrone
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Mitoxantrone
<p>Multiple Sclerosis Indicated for reducing neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis (i.e., patients whose neurologic status is significantly abnormal between relapses). It is not indicated in the treatment of patients with primary progressive multiple sclerosis.</p> <p>Prostate Cancer Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer.</p> <p>Acute Non-Lymphocytic Leukemia (ANLL) Indicated, in combination with other approved drug(s), in the initial therapy of ANLL in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.</p>

2 . Criteria

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis

Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

1.1 Secondary progressive multiple sclerosis: gradually worsening disability with or without superimposed relapses [2]

OR

1.2 Progressive relapsing multiple sclerosis: progression of disability from the onset with superimposed relapses [2]

OR

1.3 Worsening relapsing-remitting multiple sclerosis: neurological status remains significantly abnormal in between multiple sclerosis relapses [3]

AND

2 - Trial and failure, contraindication, or intolerance to two of the following disease-modifying therapies for MS: [B, 3, 11]

- Aubagio (teriflunomide)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Betaseron)
- Any one of the glatiramer acetate injections (e.g., Copaxone, Glatopa, generic glatiramer acetate)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., Gilenya, Mayzent, Zeposia)
- Any one of the B-cell targeted therapies (e.g., Kesimpta)

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm³

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone

Diagnosis	Multiple Sclerosis
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Approval Length	6 Months [5-6, A]
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140 mg/m² [1]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone

Diagnosis Prostate Cancer

Approval Length 6 Months [5-6, A]

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of advanced hormone-refractory (castration-resistant) prostate cancer

AND

2 - Used in combination with corticosteroids (e.g., prednisone, methylprednisolone) [7, 8, 10]

AND

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Neutrophil count greater than or equal to 1,500 cell/mm³

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Generic mitoxantrone

Diagnosis Prostate Cancer

Approval Length 6 Months [5-6, A]

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p> <p style="text-align: center;">AND</p> <p>2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]</p> <p style="text-align: center;">AND</p> <p>3 - A lifetime cumulative dose less than 140mg/m² [1]</p>	

Product Name: Generic mitoxantrone	
Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
Approval Length	6 Months [5-6, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with other medications used for the treatment of ANLL [9, 10]</p> <p style="text-align: center;">AND</p>	

3 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Generic mitoxantrone

Diagnosis	Acute Non-Lymphocytic Leukemia (ANLL)
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Approval Length	6 Months [5-6, A]
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Left ventricular ejection fraction (LVEF) greater than or equal to 50% [2, 4-6]

AND

3 - A lifetime cumulative dose less than 140mg/m² [1]

3 . Endnotes

- A. All patients should be carefully assessed for cardiac signs and symptoms by history and physical examination prior to start of Novantrone therapy. Left ventricular ejection fraction (LVEF) should be evaluated prior to administration of the initial dose of mitoxantrone and all subsequent doses. Mitoxantrone is recommended to be dosed once every three months. Additional doses of mitoxantrone should not be administered to multiple sclerosis patients who have experienced either a drop in LVEF to below 50% or a clinically significant reduction in LVEF during mitoxantrone therapy. [1]

- B. Per 2018 American Academy of Neurology (AAN) Multiple Sclerosis (MS) guideline, mitoxantrone should not be prescribed to people with MS due to the high frequency of severe adverse effects unless the potential benefit greatly outweighs the risk. Another MS agent that has relatively more side effects include Lemtrada and its prescribing information recommends reserving use after two prior lines of therapies have been tried. Due to this, a requirement of two prior agents for Mitoxantrone would be more appropriate to align with other MS agents that have more risks than benefit. [11]

4 . References

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Mulpleta (lusutrombopag)

Prior Authorization Guideline

Guideline Name	Mulpleta (lusutrombopag)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Mulpleta	
Approval Length	1 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of thrombocytopenia AND 2 - Baseline platelet count is less than 50,000/mcL AND	

3 - Patient has chronic liver disease

AND

4 - Patient is scheduled to undergo a procedure

2 . References

1. Mulpleta Prescribing Information. Shionogi & Co., Ltd. Florham Park, NJ. July 2018.

Prior Authorization Guideline

Guideline Name	Multiple Sclerosis (MS) Agents
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Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Avonex (interferon beta-1a)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Bafiertam (monomethyl fumarate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Betaseron (interferon beta-1b)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Drug Name: Copaxone (glatiramer acetate), Glatopa (glatiramer acetate)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Extavia (interferon beta-1b)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Kesimpta (ofatumumab)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Mavenclad (cladribine)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Limitations of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.

Drug Name: Mayzent (siponimod)

Relapsing forms of MS Indicated for the treatment of relapsing forms of MS, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Plegridy (peginterferon beta-1a)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Ponvory (ponesimod)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Rebif (interferon beta-1a)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Drug Name: Vumerity (diroximel fumarate)

Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

2 . Criteria

Product Name: Avonex, Generic glatiramer acetate, Extavia, Generic fingolimod, Kesimpta*, Plegridy	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a neurologist</p>	
Notes	*For Kesimpta, there is a QL Override (For new starts only): Please enter 2 PAs as follows with the same start date: First PA: Approve 3 syringes or pens per 28 days for the first month (Loading dose has a MDD of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no overrides needed) for 12 months. (Kesimpta is hard-coded with a quantity of 1 syringe or pen per 28 days; 0.4 mL per 20 mg pen or syringe. Maintenance dose has a MDD of 0.02)

Product Name: Brand Copaxone, Glatopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to generic glatiramer acetate

Product Name: Betaseron, Bafiertam, Mayzent, Ponvory, Rebif

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 For continuation of therapy

OR

2.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Teriflunomide
- Avonex (interferon beta-1a)
- Generic glatiramer acetate
- Extavia (interferon beta-1b)
- Fingolimod
- Kesimpta (ofatumumab)
- Plegridy (peginterferon beta-1a)
- Dimethyl fumarate
- Zeposia (ozanimod)

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Vumerity	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A-D]</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to generic dimethyl fumarate</p> <p style="text-align: center;">AND</p> <p>3 - Not used in combination with another disease-modifying therapy for MS [B, 6, 7]</p>	

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Avonex, Bafiertam, Betaseron, Brand Copaxone, Extavia, Generic glatiramer acetate, Glatopa, Generic fingolimod, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Vumerity

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)

AND

2 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad

Approval Length	2 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of a relapsing form of MS (e.g., relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has not been previously treated with cladribine

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Teriflunomide
- Plegridy (peginterferon beta-1a)
- Tysabri (natalizumab)
- Any one of the interferon beta-1a injections (e.g., Avonex)
- Any one of the interferon beta-1b injections (e.g., Extavia)
- Generic glatiramer acetate
- Any one of the B-cell targeted therapies (e.g., Kesimpta)
- Any one of the oral fumarates (e.g., generic dimethyl fumarate)
- Any one of the Sphingosine 1-Phosphate (S1P) receptor modulators (e.g., fingolimod, Zeposia)

OR

2.2 Both of the following:

2.2.1 Patient has previously received treatment with cladribine

AND

2.2.2 Patient has not already received the FDA-recommended lifetime limit of 2 treatment courses (or 4 treatment cycles total) of cladribine

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

3 . Endnotes

- A. According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [7] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [6]
- B. Initiation of treatment with an interferon beta medication or glatiramer acetate should be considered as soon as possible following a definite diagnosis of MS with active, relapsing disease, and may also be considered for selected patients with a first attack who are at high risk of MS. [6]
- C. Based on several years of experience with glatiramer acetate and interferon beta 1a and 1b, it is the consensus of researchers and clinicians with expertise in MS that these agents are likely to reduce future disease activity and improve quality of life for many individuals with relapsing forms of MS, including those with secondary progressive disease who continue to have relapses. For those who are appropriate candidates for one of these drugs, treatment must be sustained for years. Cessation of treatment may result in a resumption of pre-treatment disease activity. [6]
- D. MS specialists will use Copaxone in relapsing forms of disease, including SPMS with relapses. While there have been no trials of Copaxone in SPMS (so we have no evidenced-based data upon which to make decisions or recommendations), it's clear that where there are relapses, the injectable therapies are partially effective – they reduce relapses and new lesions on MRI. In SPMS, the trials suggest that the interferons work better in earlier, more inflammatory (i.e. those with relapses prior to the trial and with gadolinium-enhancing lesions, which is the MRI equivalent of active inflammation). Since Copaxone and the interferons appear to have rather similar efficacy in the head-to-head trials, most assume that Copaxone has a similar efficacy in SPMS: where there are relapses or active inflammation on MRI, it will likely have some benefit. Thus, most MS specialists will use Copaxone in patients with SPMS who have persistent relapses. [8]
- E. Not to exceed the FDA-recommended dosage of 2 treatment courses (with the second course administered 43 weeks following the last dose of the first course). According to Prescribing Information, the recommended cumulative dosage of Mavenclad is 3.5 mg per kg body weight administered orally and divided into 2 yearly treatment courses (1.75 mg per kg per treatment course). Each treatment course is divided into 2 treatment cycles with the second cycle of each course administered 23 to 27 days after the last dose of the first cycle. Following the administration of 2 treatment courses, do not administer additional Mavenclad treatment during the next 2 years. Treatment during these 2 years may further increase the risk of malignancy. The safety and efficacy of reinitiating Mavenclad more than 2 years after completing 2 treatment courses has not been studied. [14]
- F. The advantage of using combination disease-modifying therapy (DMT) compared to monotherapy DMT use has not been demonstrated, but there are safety concerns, such as reduced efficacy or disease aggravation, with combination use. [18, 19]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. November 2021.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. November 2021.
3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. January 2022.
4. Extavia Prescribing Information. Novartis. East Hanover, NJ. October 2020.
5. Rebif Prescribing Information. Serono Inc. Rockland, MA. October 2020.
6. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurology* 2018;90:777-788.
7. National Multiple Sclerosis Society. Types of MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Types-of-MS>. Accessed March 29, 2019.
8. Per clinical consultation with MS specialist, December 29, 2010.
9. Plegridy Prescribing Information. Biogen Idec Inc. Cambridge, MA. January 2021.
10. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. January 2020.
11. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2021.
12. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. April 2019.
13. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. January 2021.
14. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. April 2020.
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18. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. *Mayo Clinic Proceedings*, 89(2), 225-240.
19. Sorensen, P., Lycke, J., Erälinna, J., Edland, A., Wu, X., & Frederiksen, J. et al. (2011). Simvastatin as add-on therapy to interferon beta-1a for relapsing-remitting multiple sclerosis (SIMCOMBIN study): a placebo-controlled randomised phase 4 trial. *The Lancet Neurology*, 10(8), 691-701.

Myalept (metreleptin for injection)

Prior Authorization Guideline

Guideline Name	Myalept (metreleptin for injection)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of congenital or acquired generalized lipodystrophy AND 2 - Patient is refractory to current standards of care for lipid and diabetic management	

AND

3 - Prescribed by or in consultation with an endocrinologist

AND

4 - Documentation demonstrates that patient has at least one of the following metabolic abnormalities:

- Insulin resistance (defined as requiring more than 200 units per day)
- Hypertriglyceridemia
- Diabetes

Product Name: Myalept	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to Myalept therapy, such as one of the following:	
<ul style="list-style-type: none">• Sustained reduction in hemoglobin A1c level from baseline• Sustained reduction in triglyceride levels from baseline	

2 . References

1. Myalept Prescribing Information. Aegerion Pharmaceuticals, Inc. Cambridge, MA. September 2015.

Myobloc (rimabotulinumtoxin B)

Prior Authorization Guideline

Guideline Name	Myobloc (rimabotulinumtoxin B)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Myobloc (rimabotulinumtoxin B)
Cervical Dystonia (CD) Indicated for the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.
Chronic Sialorrhea Indicated for the treatment of chronic sialorrhea in adults.

2 . Criteria

Product Name: Myobloc	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [2]

Product Name: Myobloc

Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
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Approval Length	3 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

AND

2 - At least 3 months have elapsed since the last treatment [A]

Product Name: Myobloc

Diagnosis	Chronic Sialorrhea
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Approval Length	3 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of chronic sialorrhea

Product Name: Myobloc

Diagnosis	Chronic Sialorrhea
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Approval Length	3 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy.</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have elapsed since the last treatment [B]</p>	

3 . Endnotes

- A. The duration of effect in patients responding to Myobloc treatment has been observed in studies to be between 12 and 16 weeks at doses of 5,000 Units or 10,000 Units. [1]
- B. The typical duration of effect of each treatment is up to 3 months with the repeat of treatments should be determined by clinical response but should generally be no frequent than every 12 weeks.

4 . References

1. Myobloc Prescribing Information. Solstice Neurosciences, LLC. Louisville, KY. March 2021.
2. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016 May;86(19):1818-26.

Natpara (parathyroid hormone)

Prior Authorization Guideline

Guideline Name	Natpara (parathyroid hormone)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Natpara	
Approval Length	4 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Diagnosis of hypocalcemia</p> <p style="text-align: center;">AND</p> <p>1.2 Hypocalcemia is due to chronic hypoparathyroidism</p>	

AND

2 - Not used in the setting of acute post-surgical hypoparathyroidism

AND

3 - Patient does not have a known calcium-sensing receptor mutation

AND

4 - Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months

AND

5 - Prescribed by or in consultation with an endocrinologist [C]

AND

6 - Patient has been optimized on adequate doses of both of the following supplements [A]:

- Calcium (greater than or equal to 2,000 mg daily)
- Vitamin D (calcitriol greater than or equal to 1 mcg/day)

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Patient is not on thyroid hormone replacement therapy

AND

7.1.2 Patient has normal thyroid-stimulating hormone concentrations

OR

7.2 Both of the following:

7.2.1 Patient is on thyroid hormone replacement therapy

AND

7.2.2 Patient's thyroid hormone replacement therapy dose has been stable for greater than or equal to 3 months

AND

8 - Patient has normal serum concentrations of both of the following:

- Magnesium
- 25-hydroxyvitamin D

AND

9 - One of the following:

9.1 Creatinine clearance (CrCL) is greater than or equal to 30 mL/min on two separate measurements

OR

9.2 Both of the following:

9.2.1 Creatinine clearance (CrCL) > 60 mL/min on one measurement

AND

9.2.2 Serum creatinine (SCr) < 1.5 mg/dL

AND

10 - Used as an adjunct to calcium and vitamin D [B]

Product Name: Natpara	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following:	
1.1 Patient has achieved and maintained serum calcium levels in the ideal range (8 - 9 mg/dL)	
OR	
1.2 Patient has experienced a 50% or greater reduction in oral calcium intake	
OR	
1.3 Patient has experienced a 50% or greater reduction in oral vitamin D intake	

2 . Background

Benefit/Coverage/Program Information
Quantity Limit

This product is subject to an OptumRx standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.

3 . Endnotes

- A. Due to a potential risk of osteosarcoma, Natpara use should be limited to those who do not respond to standard of care therapy with calcium and active vitamin D supplementation. [3]
- B. In the REPLACE trial, patients were initiated on Natpara therapy with both calcium supplements and active vitamin D. During the 12-week titration phase, the doses of active vitamin D were reduced and, if possible, eliminated, followed by a reduction in oral calcium doses, while maintaining serum calcium at or above the concentration recorded at baseline. [2]
- C. Prescriber certification is required through the Natpara REMS program. [4]

4 . References

1. Natpara Prescribing Information. Shire-NPS Pharmaceuticals Inc. Lexington, MA. August 2018.
2. Mannstadt M, Clarke BL, Vokes T, et al. Efficacy and safety of recombinant human parathyroid hormone (1-84) in hypoparathyroidism (REPLACE): a double blind, placebo-controlled, randomized phase 3 study. *Lancet*. 2013; 1:275-83.
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4. Natpara Risk Evaluation and Mitigation Strategy (REMS). Food and Drug Administration Web Site. 2015. <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM431974.pdf>. Accessed September 19, 2018.
5. Sikjaer T, Rejnmark L, Rolighed L, et al. The effect of adding PTH(1-84) to conventional treatment of hypoparathyroidism: a randomized, placebo-controlled study. *J Bone Miner Res*. 2011;26(10):2358-70.
6. Bilezikian JP, Khan A, Potts JT Jr, et al. Hypoparathyroidism in the adults: epidemiology, diagnosis, pathophysiology, target-organ involvement, treatment, and challenges for future research. *J Bone Mineral Res*. 2011; 26(10): 2317-2337.
7. Winer KK, Ko CW, Reynolds JC, et al. Long-Term Treatment of Hypoparathyroidism: A Randomized Controlled Study Comparing Parathyroid Hormone-(1-34) Versus Calcitriol and Calcium. *J Clin Endocrinol Metab*. 2003;88(9):4214-4220.
8. Winer KK, Sinai N, Reynolds JC, et al. Long-Term Treatment of 12 Children with Chronic Hypoparathyroidism: A Randomized Trial Comparing Synthetic Human Parathyroid Hormone 1-34 versus Calcitriol and Calcium. *J Clin Endocrinol Metab*. 2010 Jun; 95(6): 2680-2688.

Nerlynx (neratinib)

Prior Authorization Guideline

Guideline Name	Nerlynx (neratinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Nerlynx (neratinib)
Early Stage Breast Cancer Indicated for the extended adjuvant treatment of adult patients with early-stage human epidermal growth factor receptor 2 (HER2)-positive breast cancer, to follow adjuvant trastuzumab based therapy
Advanced or Metastatic Breast Cancer Indicated for the treatment of adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting in combination with capecitabine.

2 . Criteria

Product Name: Nerlynx	
Diagnosis	Early Stage Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of early stage breast cancer

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Treatment duration of Nerlynx has not exceeded a total of 12 months [1, 2, 3, A]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of advanced or metastatic breast cancer	
AND	
2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive	

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Nerlynx	
Diagnosis	Advanced or Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Per the ExteNET Lancet study, Nerlynx was administered for no more than 12 months and showed improvement in disease-free survival in trastuzumab (Herceptin)-treated patients with early breast cancer. [2]

4 . References

1. Nerlynx Prescribing Information. Puma Biotechnology, Inc. Los Angeles, CA. July 2021.
2. Chan A, Delaloge S, Holmes FA, et al. Neratinib after trastuzumab-based adjuvant therapy in patients with HER2-positive breast cancer (ExteNET): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Oncol* 2016; 17: 367-77.
3. Per Clinical Consultation with an Oncologist, August 24th, 2017.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.7.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 7, 2021.
5. Saura C, Garcia-Saenz JA, Xu B, et al. Safety and efficacy of neratinib in combination with capecitabine in patients with metastatic human epidermal growth factor receptor 2-positive breast cancer. *J Clin Oncol*. 2014 Nov 10;32(32):3626-33. doi: 10.1200/JCO.2014.56.3809.

6. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 7, 2022.

Prior Authorization Guideline

Guideline Name	New Drug to Market Program - PA, NF
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Guideline Note:

Effective Date:	2/15/2023
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Note:

Only applies to the OPEN Group Choice Formulary (SWHPOGC and SWHPNRX)

1 . Criteria

Product Name: Drugs included on the New Drug to Market list for which a Drug-Specific Prior Authorization Guideline is Unavailable*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization, Non-Formulary
Approval Criteria 1 - One of the following: 1.1 All of the following: 1.1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication	

AND

1.1.2 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.3 Requested drug will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - One of the following:

2.1 Patient has failed or has contraindications or intolerance to at least three covered, lower tier drugs**. If only one or only two drugs are available, the patient must have failed or had contraindications or intolerance to all available covered, lower tier drugs. The clinician's judgment should be used to determine covered, lower tier drugs for the indication provided.

OR

2.2 Both of the following:

2.2.1 Only over-the-counter (OTC) equivalents are available

AND

2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

2.3 No formulary or OTC drug is appropriate to treat the patient's condition

Notes

* Drug should be reviewed using the drug-specific Prior Authorization guideline if available, regardless of if the drug requires Prior Authorization or Non-Formulary review. If no drug-specific Prior Authorization guideline is available, proceed with the criteria above. This guideline should not be used to address step therapy. ** Lower tier drugs would be applicable to reject 75's (PA required drugs).

Nexavar (sorafenib)

Prior Authorization Guideline

Guideline Name	Nexavar (sorafenib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Nexavar (sorafenib)
Renal Cell Carcinoma Indicated for the treatment of patients with advanced renal cell carcinoma (RCC).
Hepatocellular Carcinoma Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC).
Differentiated Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid carcinoma (DTC) that is refractory to radioactive iodine treatment.

2 . Criteria

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma
Approval Length	12 Months [A]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of advanced renal cell carcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Oncologist • Nephrologist <p style="text-align: center;">AND</p> <p>3 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)</p>	

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma
Approval Length	12 Months [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - Prescribed by or in consultation with one of the following:

- Oncologist
- Hepatologist
- Gastroenterologist

AND

3 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Differentiated Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of differentiated thyroid carcinoma

AND

2 - One of the following:

- Locally recurrent disease
- Metastatic disease

AND

3 - Patient has progressive disease

AND

4 - Disease is refractory to radioactive iodine (RAI) treatment

AND

5 - Prescribed by or in consultation with an oncologist

AND

6 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Differentiated Thyroid Carcinoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. Treatment should continue until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity occurs. Mean progression-free survival in Study 1 as described in the Nexavar prescribing information indicates a median progression-free survival of 167 days in Nexavar-treated patients with renal cell carcinoma. [1]

4 . References

1. Nexavar Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. July 2020.
2. Brose MS, Nutting CM, Sherman SI, et al. Rationale and design of DECISION: a doubleblind, randomized, placebo-controlled phase III trial evaluating the efficacy and safety of sorafenib in patients with locally advanced or metastatic radioactive iodine (RAI)-refractory, differentiated thyroid cancer. *BMC Cancer*. 2011;349.
3. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. <https://www.nccn.org>. Accessed April 3, 2021.
4. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. V.2.2020. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2020.
5. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Hepatobiliary Cancers. V.2.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
6. National Comprehensive Cancer network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. V.1.2021. NCCN Website. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed April 3, 2021
7. Sorafenib Prescribing Information. Dr. Reddys Laboratories Inc. Princeton, NJ. June 2022.

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)

Prior Authorization Guideline

Guideline Name	Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Nexletol (bempedoic acid), Nexlizet (bempedoic acid-ezetimibe)
HeFH or ASCVD Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. Limitations of Use: The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [11]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization (e.g., percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery)
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of one HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of one MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of one LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following LDL-C values while on maximally tolerated statin therapy within the last 120 days: [6-9]

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - One of the following: [D]

4.1 Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy [A]

OR

4.2 Patient has a history of contraindication or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in LDL-C levels)</p> <p>AND</p> <p>2 - One of the following:</p> <p>2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose</p> <p>OR</p> <p>2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)</p>	

3 . Endnotes

- A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [5]

- B. In the Nexletol and Nexlizet pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-4]
- C. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [5]
- D. The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined. Outcomes trials evaluating the efficacy of bempedoic acid are currently underway. In contrast, IMPROVE-IT was a prospective randomized controlled trial evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). The 2017 ACC/AHA non-statin decision pathway update recommends that for patients who are maximized on statin therapy with baseline LDL-C 70-189 mg/dL, it is reasonable to consider the addition of ezetimibe. In patients with clinical ASCVD who are judged to be very high risk with LDL-C 70 mg/dL or higher, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe. [5, 8-9]

4 . References

1. Nexletol Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. February 2020.
2. Nexlizet Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. November 2020.
3. WHO Familial Hypercholesterolemia Consultation Group. Familial Hypercholesterolemia (FH): report of a second WHO consultation. Geneva: World Health Organization; 1999.
4. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolemia. *BMJ*. 1991;303:893-6.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73:e285-e350.
6. ATP III Final Report PDF. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. *Circulation*. 2002;106:3143-3421.
7. Per clinical drug consult with cardiologist. August 3, 2015.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol*. 2017;70:1785-1822.
9. Goldberg AC, Hopkins PN, Toth PP, et al. Familial hypercholesterolemia: screening, diagnosis, and management of pediatric and adult patients: clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J Clin Lipidol*. 2011;5:S1-51.
10. Cannon CP, Blazing MA, Giugliano RP, et al. Ezetimibe added to statin therapy after acute coronary syndromes. *N Engl J Med*. 2015;372:2387-97.
11. Per clinical drug consult with cardiologist. November 17, 2017.

Ninlaro (ixazomib citrate)

Prior Authorization Guideline

Guideline Name	Ninlaro (ixazomib citrate)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Ninlaro (ixazomib citrate)
Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy. Limitations of Use: NINLARO is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.

2 . Criteria

Product Name: Ninlaro	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of multiple myeloma

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ninlaro

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Ninlaro Prescribing Information. Takeda Pharmaceutical Company Limited. Cambridge, MA. November 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at <http://www.nccn.org>. Accessed May 31, 2022.

Prior Authorization Guideline

Guideline Name	Nityr and Orfadin
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Nityr (nitisinone) tablets
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.
Drug Name: Brand Orfadin capsules, Brand Orfadin oral suspension, Generic nitisinone capsules
Hereditary Tyrosinemia Type 1 (HT-1) Indicated for the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

2 . Criteria

Product Name: Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hereditary tyrosinemia type 1 (HT-1)</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis confirmed by the presence of succinylacetone in the plasma or urine [1-3]</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with dietary restriction of tyrosine and phenylalanine</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Gastroenterologist • Hepatologist • Other specialist with experience in treating inborn errors of metabolism <p style="text-align: center;">AND</p> <p>5 - Both of the following (applies to BRAND Orfadin only):</p> <p>5.1 Trial and failure or intolerance to generic nitisinone</p> <p style="text-align: center;">AND</p> <p>5.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug 	

<ul style="list-style-type: none"> Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	
Notes	<p>*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.</p>

Product Name: Nityr*, Brand Orfadin, Generic nitisinone	
Diagnosis	Hereditary Tyrosinemia type 1 (HT-1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following (applies to BRAND Orfadin only):</p> <p>2.1 Trial and failure or intolerance to generic nitisinone</p> <p style="text-align: center;">AND</p> <p>2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> Allergic response or intolerance to one of the inactive ingredients of the generic drug Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) 	

Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and administered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For preparation and administration instructions, see the full prescribing information.
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3 . References

1. Nityr Prescribing Information. Cycle Pharmaceuticals Ltd. Cambridge, UK. November 2018.
2. Orfadin Prescribing Information. Sobi Inc. Waltham, MA. May 2019.
3. de Laet C, Dionisi-Vici C, Leonard JV, et al. Recommendations for the management of tyrosinaemia type 1. Orphanet J Rare Dis. 2013;8:8.

Nocdurna (desmopressin)

Prior Authorization Guideline

Guideline Name	Nocdurna (desmopressin)
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Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Nocdurna (desmopressin acetate sublingual tablet)
Nocturia Indicated for the treatment of nocturia due to nocturnal polyuria in adults who awoken at least 2 times per night to void. In the Nocdurna clinical trials nocturnal polyuria was defined as night-time urine production exceeding one-third of the 24-hour urine production. Before starting Nocdurna: (1) Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and address other treatable causes of nocturia. (2) Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

2 . Criteria

Product Name: Nocdurna	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nocturia due to nocturnal polyuria

AND

2 - Nighttime urine production exceeds one-third of the 24-hour urine production [A]

AND

3 - Patient wakes at least twice per night on a reoccurring basis to void

AND

4 - Initial serum sodium level prior to initiating therapy is within normal limits of the normal laboratory reference range

AND

5 - One of the following: [B]

5.1 Underlying causes of nocturia have been ruled out (e.g., overactive bladder, benign prostatic hyperplasia (BPH), Parkinson’s disease, excessive bedtime fluid intake)

OR

5.2 Underlying medical causes of nocturia are treated prior to initiating therapy (e.g., use of alpha-adrenergic blockers or 5-alpha reductase inhibitors for BPH, vaginal estrogens for vaginal atrophy)

Product Name: Nocdurna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p data-bbox="198 352 435 384">Approval Criteria</p> <p data-bbox="198 422 938 453">1 - Documentation of positive clinical response to therapy</p> <p data-bbox="776 527 841 558" style="text-align: center;">AND</p> <p data-bbox="198 632 945 663">2 - Patient has routine monitoring for serum sodium levels</p>	

3 . Endnotes

- A. In clinical trials, nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. [1]
- B. Prior to initiating treatment, patients should be evaluated for possible causes of nocturia and to optimize the treatment of underlying conditions that may be contributing to the nocturia. [1]

4 . References

1. Nocdurna Prescribing Information. Antares Pharma, Inc. Ewing, NJ. August 2021.

Prior Authorization Guideline

Guideline Name	Non-Formulary Drug Exceptions Process
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Guideline Note:

Effective Date:	3/15/2024
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1 . Criteria

Product Name: A non-formulary contraceptive drug	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <ul style="list-style-type: none">• Patient is using the requested product for contraception or other FDA-approved condition*• The requested product is medically necessary** <p style="text-align: center;">OR</p>	

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes

*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. **Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.

Product Name: A non-formulary drug

Approval Length

12 month(s)

Guideline Type

Administrative

Approval Criteria

1 - In the absence of a drug-specific non-formulary guideline that has been approved by the P&T Committee to guide the non-formulary exceptions process, the following general guideline will be used to establish medical necessity:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Patient has failed or has contraindications or intolerance to at least three equivalent formulary drugs. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available equivalent formulary drugs. The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided (if request is for a combination product, member must have documentation indicating concurrent use of separate agents).

AND

1.1.1.2 If the requested drug is for a multi-source brand medication (i.e., MSC O), BOTH of the following:

1.1.1.2.1 Patient has had a trial and failure, contraindication, or intolerance to the generic product

AND

1.1.1.2.2 Submission of documentation (chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

OR

1.1.2 Both of the following:

1.1.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.1.2.2 Patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.

OR

1.1.3 No formulary or OTC drug is appropriate to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Prior Authorization Guideline

Guideline Name	Non-steroidal Anti-Inflammatory Agents
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Cambia (diclofenac) powder
Migraine Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.
Drug Name: Sprix (ketorolac tromethamine) nasal spray
Moderate to moderately severe pain Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the opioid level. Limitations of Use: Sprix is not for use in pediatric patients less than 2 years of age.
Drug Name: Tivorbex (indomethacin) capsules
Mild to moderate pain Indicated for treatment of mild to moderate acute pain in adults.
Drug Name: Pennsaid (diclofenac sodium) topical solution, Klofensaid (diclofenac sodium) topical solution
Osteoarthritis (OA) Indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).

Drug Name: Indocin

Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.

Drug Name: Vivlodex

Osteoarthritis (OA) Indicated for the treatment of osteoarthritis (OA) pain.

Drug Name: Zorvolex

Pain Indicated for the treatment of mild to moderate acute pain and management of osteoarthritis (OA) pain.

Drug Name: Qmiiz ODT

Osteoarthritis (OA), Rheumatoid Arthritis (RA), Juvenile rheumatoid arthritis (JRA) Indicated for the treatment of osteoarthritis (OA), rheumatoid arthritis (RA) in adults, and Juvenile rheumatoid arthritis (JRA) Pauciarticular and polyarticular course in pediatric patients who weigh greater than or equal to 60 kg

2 . Criteria

Product Name: Sprix nasal spray, Brand Ketorolac nasal spray

Approval Length 5 Days [A]

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to moderately severe pain

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets

OR

2.2 Patient is unable to take medications orally

Notes

*Ketorolac is recommended only for patients less than 65 years old. [B, C]

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution, Klofensaid

Approval Length 12 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of osteoarthritis of the knee(s)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to at least two prescription strength oral NSAIDs (e.g., diclofenac, diclofenac ER, ibuprofen, indomethacin, etc.)

OR

2.2 Documented swallowing disorder

OR

2.3 History of peptic ulcer disease/gastrointestinal bleed

OR

2.4 Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution, Klofensaid

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., improvement in pain symptoms of osteoarthritis) to therapy

Product Name: Tivorbex*, Brand Indomethacin 20mg, Cambia**^, Indocin, Vivlodex, Zorvolex

Approval Length | 12 month(s)

Guideline Type | Step Therapy

Approval Criteria

1 - Trial and failure, contraindication, or intolerance to two of the following:

- diclofenac or diclofenac ER
- diflunisal
- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meclofenamate
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac

<ul style="list-style-type: none"> tolmetin 	
Notes	<p>*Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including indomethacin, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] **Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including diclofenac, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B]</p> <p>^Product may be excluded depending on the plan.</p>

3 . Endnotes

- A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [1]
- B. This drug is included on the 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [3]
- C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [4]

4 . References

1. Sprix Prescribing Information. Egalet US Inc. Wayne, PA. January 2018.
2. Pennsaid Prescribing Information. Horizon Pharma USA Inc. Lake Forest, IL. May 2016.
3. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2012 Apr;60(4):616-31.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed September 10, 2014.
5. Tivorbex Prescribing Information. Iroko Pharmaceuticals LLC, Philadelphia, PA. January 2018.
6. Cambia Prescribing Information. Depomed, Inc, Newark, CA. March 2017.
7. Vivlodex Prescribing Information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. October 2015.
8. Indocin Prescribing Information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. May 2016.
9. Zorvolex Prescribing Information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. May 2016.

10. Qmiiz ODT Prescribing Information. TerSera Therapeutics LLC. Lake Forest, IL. October 2018.

Northera (droxidopa)

Prior Authorization Guideline

Guideline Name	Northera (droxidopa)
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Northera (droxidopa)
Neurogenic orthostatic hypotension (NOH) Indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (NOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of Northera should be assessed periodically.

2 . Criteria

Product Name: Brand Northera, Generic droxidopa	
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of symptomatic neurogenic orthostatic hypotension (NOH)

AND

2 - NOH is caused by one of the following conditions:

- Primary autonomic failure (e.g., Parkinson's disease, multiple system atrophy, pure autonomic failure)
- Dopamine beta-hydroxylase deficiency
- Non-diabetic autonomic neuropathy

AND

3 - Prescribed by or in consultation with one of the following specialists: [2, A]

- Cardiologist
- Neurologist
- Nephrologist

AND

4 - Attempt has been made to manage NOH through at least one non-pharmacologic intervention (e.g., use of compression stockings/abdominal binder, increasing salt/fluid intake, patient participates in regular exercise, discontinue or reduce hypotensive or antihypertensive medications) [2, 4, 5, B]

AND

5 - Trial and failure, contraindication, or intolerance to one of the following agents:

- Fludrocortisone acetate [2, 3]
- Midodrine [2, 3]

AND

6 - Both of the following (applies to BRAND Northera only):

6.1 Trial and failure or intolerance to generic droxidopa

AND

6.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Northera, Generic droxidopa

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

AND

2 - Both of the following (applies to BRAND Northera only):

2.1 Trial and failure or intolerance to generic droxidopa

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug

- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . Endnotes

- A. Per consultant recommendation, prescribers who are best able to manage blood pressure or neurological conditions, like NOH, include cardiologists, neurologists, and nephrologists. [4]
- B. According to international treatment guidelines, as well as per consultant recommendation, NOH should be managed non-pharmacologically before using medications, such as fludrocortisone, midodrine, or droxidopa, to treat NOH directly. This requirement of non-pharmacologic intervention is not possible for Medicare due to benefit design, and will therefore be applicable to Commercial plans only. [2, 4, 5]

4 . References

1. Northera Prescribing Information. Lundbeck. Deerfield, IL. July 2019
2. Berger MJ, Kimpinski K. A practical guide to the treatment of neurogenic orthostatic hypotension. *Can J Neurol Sci.* 2014;41:156-163.
3. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Accessed March 31, 2020
4. Per Clinical Consultation with a Neurologist. July 7, 2014.
5. Freeman R. Neurogenic orthostatic hypotension. *N Engl J Med.* 2008; 358:615-24.

Nourianz (istradefylline)

Prior Authorization Guideline

Guideline Name	Nourianz (istradefylline)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Nourianz (istradefylline)
Parkinson's Disease Indicated as adjunctive treatment to levodopa/carbidopa in adults patients with Parkinson's disease (PD) experiencing "off" episodes.

2 . Criteria

Product Name: Nourianz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Parkinson's disease	

AND

2 - Patient is experiencing "off" episodes

AND

3 - Used in combination with carbidopa/levodopa at a maximally tolerated dose

AND

4 - Trial and failure, contraindication or intolerance to two of the following:

- MAO-B Inhibitor (e.g., rasagiline, selegiline)
- Dopamine Agonist (e.g., pramipexole, ropinirole)
- COMT Inhibitor (e.g., entacapone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Nourianz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	
AND	
2 - Used in combination with carbidopa/levodopa	

3 . References

1. Nouriaz Prescribing Information. Kyowa Kirin, Inc. Bedminster, NJ. August 2019.

Nubeqa (darolutamide)

Prior Authorization Guideline

Guideline Name	Nubeqa (darolutamide)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Nubeqa (darolutamide)
Non-metastatic castration-resistant prostate cancer Indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).
Metastatic hormone-sensitive prostate cancer (mHSPC) Indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

2 . Criteria

Product Name: Nubeqa	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer (CRPC)

AND

2 - Prescribed by or in consultation with an oncologist or urologist

Product Name: Nubeqa	
Diagnosis	Hormone-sensitive prostate cancer (HSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hormone-sensitive prostate cancer (HSPC)	
AND	
2 - Prescribed by or in consultation with an oncologist or urologist	

Product Name: Nubeqa	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Nubeqa Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. August 2022.
2. Klotz L, O'Callaghan C, Ding K, et al. Nadir testosterone within first year of androgen-deprivation therapy (ADT) predicts for time to castration-resistant progression: a secondary analysis of the PR-7 trial of intermittent versus continuous ADT. *J Clin Oncol* 2015;33:1151-56. doi:10.1200/JCO.2014.58.2973.
3. Smith, M., Hussain, M. et al. Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer. Available at https://www.nejm.org/doi/10.1056/NEJMoa2119115?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed. Accessed August 13, 2022.

Nucala (mepolizumab)

Prior Authorization Guideline

Guideline Name	Nucala (mepolizumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Nucala (mepolizumab)
Severe Eosinophilic Asthma Indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.
Eosinophilic Granulomatosis with Polyangiitis Indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
Hypereosinophilic Syndrome Indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

2 . Criteria

Product Name: Nucala

Diagnosis	Severe Asthma
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe asthma [1, A]

AND

2 - Asthma is an eosinophilic phenotype as defined by one of the following [1, 3, B]:

- Baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter
- Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months

AND

3 - One of the following:

3.1 Patient has had at least one or more asthma exacerbations requiring systemic corticosteroids within the past 12 months [2-4, H]

OR

3.2 Any prior intubation for an asthma exacerbation

OR

3.3 Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications [2-4, D]:

4.1 Both of the following:

- High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol])

AND

5 - Age greater than or equal to 6 years [1]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Severe Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations,	

improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications) [C]

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)	
AND	
2 - Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [10, 11]	
AND	

3 - Presence of at least 2 of the following symptoms for at least 12 weeks:

- Nasal blockage/obstruction/congestion
- Nasal discharge (anterior/posterior nasal drip)
- Facial pain/pressure
- Reduction or loss of smell

AND

4 - Systemic corticosteroid treatment for nasal polyps at least once in the last two years or prior nasal polyp surgery > 6 months ago

AND

5 - Used in combination with another agent for CRSwNP [J]

AND

6 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Chronic rhinosinusitis with nasal polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale])	

AND

2 - Used in combination with another agent for CRSwNP [J]

AND

3 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)	
AND	
2 - Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy) [F, 7]	
AND	
3 - Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) [F, 7]	

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Rheumatologist
- Allergist/Immunologist

Product Name: Nucala	
Diagnosis	Eosinophilic Granulomatosis with Polyangiitis (EGPA)
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., increase in remission time)	

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hypereosinophilic syndrome (HES)	
AND	
2 - Patient has been diagnosed for at least 6 months	

AND

3 - Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)

AND

4 - Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFR α)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [!]
- Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter

AND

6 - Trial and failure, contraindication, or intolerance to one of the following:

- Corticosteroid therapy (e.g., prednisone)
- Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib)

AND

7 - Prescribed by or in consultation with one of the following:

- Allergist/Immunologist
- Hematologist

Product Name: Nucala	
Diagnosis	Hypereosinophilic Syndrome (HES)
Approval Length	12 Months

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)	

3 . Background

Clinical Practice Guidelines			
The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [6]			
Inhaled corticosteroid	Total Daily ICS Dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.

This is not a table of equivalence, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.

For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.

4 . Endnotes

- A. Patients included across the 3 pivotal studies (DREAM, MENSA, and SIRIUS) [2-4] were characterized with clinical features of severe refractory asthma per American Thoracic Society (ATS) criteria [5]. Per the ATS: "Severe asthma is defined as asthma which requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy." This definition includes patients who received an adequate trial of these therapies in whom treatment was stopped due to lack of response. In patients greater than 6 years of age, "Gold Standard/International Guidelines treatment" is high dose ICS plus a long-acting beta 2-agonist (LABA), leukotriene modifier or theophylline and/or continuous or near continuous systemic corticosteroids as background therapy."
- B. Inclusion criteria was modified from the DREAM study to the MENSA study to be limited to patients with eosinophils greater than or equal to 150 cells/mcL in the peripheral blood at screening or greater than or equal to 300 cells/mcL at some time during the previous year [3].
- C. The primary endpoint for the DREAM and MENSA studies was the annual rate of clinically significant asthma exacerbations as a composite of the required use of systemic corticosteroids for at least 3 days, admission, or ED visit. Both studies showed mepolizumab-treated patients experienced a significant improvement in exacerbation rates compared with baseline and compared with placebo. [2, 3]
- D. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update lists anti-interleukin- 5 treatment or anti-interleukin 5 receptor treatment as an add on option for patients with severe eosinophilic asthma that is uncontrolled on two or more controllers plus as-needed reliever medication (Step 4-5 treatment). [6]
- E. Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and

magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [6].

- F. Nucala was approved for Eosinophilic Granulomatosis with Polyangiitis (EGPA) based on the results from the pivotal, 52-week, Phase III MIRRA study. MIRRA looked at the efficacy and safety of 300 mg of mepolizumab administered SQ every four weeks versus placebo as add-on therapy to standard of care (corticosteroids plus or minus immunosuppressants) in 136 patients with relapsing and/or refractory EGPA. MIRRA reported statistically significant outcomes with both co-primary endpoints (i.e., accrued time in remission and proportion of patients achieving remission) in favor of the treatment group [7, 8].
- G. The GINA Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. [6]
- H. Per P&T Committee, February 2019, revised exacerbation requirement to mirror other IL-5 antagonists.
- I. Historical flares were defined as a worsening of HES-related clinical symptoms or a blood eosinophil count requiring an escalation in therapy. [1]
- J. Other agents used for CRSwNP include intranasal corticosteroids and nasal saline.

5 . References

1. Nucala prescribing information. GlaxoSmithKline LLC. Philadelphia, PA. March 2023.
2. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicentre, double-blind, placebo-controlled trial. *Lancet*. 2012;380: 651-59.
3. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1198-1207.
4. Bel EH, Wenzel SE, Thompson PJ, et al. Oral Glucocorticoid-Sparing Effect of Mepolizumab in Eosinophilic Asthma. *N Engl J Med*. 2014;371:1189-1197.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
6. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
7. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. *N Engl J Med*. 2017;376(20):1921-1932.
8. GlaxoSmithKline Press Release. GSK achieves approval for Nucala (mepolizumab) for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) for adults in the US. Website. Available from: <https://www.gsk.com/en-gb/media/press-releases/gsk-achieves-approval-for-nucala-mepolizumab-for-the-treatment-of-eosinophilic-granulomatosis-with-polyangiitis-egpa-for-adults-in-the-us/>. Accessed March 11, 2021.
9. ClinicalTrials.gov Web site. <https://clinicaltrials.gov/ct2/show/NCT03085797>. Accessed August 15, 2021.
10. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-85.

11. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. *Int Forum Allergy Rhinol.* 2016 Feb; Suppl 1:S22-209.

Nuedexta (dextromethorphan HBr/quinidine)

Prior Authorization Guideline

Guideline Name	Nuedexta (dextromethorphan HBr/quinidine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Nuedexta (dextromethorphan HBr/quinidine)
Pseudobulbar Affect (PBA) Indicated for the treatment of pseudobulbar affect (PBA). PBA occurs secondary to a variety of otherwise unrelated neurologic conditions, and is characterized by involuntary, sudden, and frequent episodes of laughing and/or crying. PBA episodes typically occur out of proportion or incongruent to the underlying emotional state. PBA is a specific condition, distinct from other types of emotional lability that may occur in patients with neurological disease or injury.

2 . Criteria

Product Name: Nuedexta	
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pseudobulbar affect (PBA)

AND

2 - Patient has one of the following conditions: [3]

- Amyotrophic lateral sclerosis
- Multiple sclerosis
- Alzheimer's disease
- Parkinson's disease
- Stroke
- Traumatic brain injury

AND

2 - There is an absence of a cardiac rhythm disorder documented by a cardiac test (e.g., electrocardiogram)

AND

4 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Psychiatrist

Product Name: Nuedexta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of clinical benefit from ongoing therapy	

3 . Endnotes

- A. Patients should be evaluated for Nuedexta benefit after the initial 3 months of treatment.
[2]

4 . References

1. Nuedexta Prescribing Information. Avanir Pharmaceuticals, Inc. Aliso Viejo, CA. June 2019.
2. Per clinical consultation with neurologist, September 8, 2011 and October 23, 2019.
3. Pseudobulbar affect: prevalence and management. Ther Clin Risk Manag. 2013;9:483-9.

Nulibry (fosdenopterin)

Prior Authorization Guideline

Guideline Name	Nulibry (fosdenopterin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Nulibry (fosdenopterin)
Molybdenum cofactor deficiency (MoCD) Type A Indicated to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A.

2 . Criteria

Product Name: Nulibry	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Submission of documentation (e.g., chart notes) confirming both of the following:	

- Diagnosis of molybdenum cofactor deficiency (MoCD) Type A
- Genetic mutation in the MOCS1 gene

AND

2 - Patient has clinical and/or laboratory signs and symptoms consistent with MOCD Type A (e.g., seizures, limb/axial hypertonia, elevated levels of urinary sulfite/SSC [s-sulfocysteine] or xanthine in blood/urine, low uric acid in blood/urine)

AND

3 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

Product Name: Nulibry	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders</p> <p style="text-align: center;">AND</p> <p>2 - Patient continues to benefit from medication</p>	

3 . References

1. Nulibry Prescribing Information. Origin Biosciences, Inc. Boston, MA. March 2021.
2. Study of ORGN001 (formerly ALXN1101) in neonates, infants and children with molybdenum cofactor deficiency (MOCD) type A. ClinicalTrials.gov identifier: NCT02629393. Updated February 26, 2021. Accessed April 12, 2021. <https://www.clinicaltrials.gov/ct2/show/study/NCT02629393>.

3. Per clinical consultation with pediatrician, April 30, 2021.
4. Mechler, K., Mountford, W., Hoffmann, G. et al. Ultra-orphan diseases: a quantitative analysis of the natural history of molybdenum cofactor deficiency. *Genet Med* 17, 965–970 (2015). <https://doi.org/10.1038/gim.2015.12>

Ocaliva (obeticholic acid)

Prior Authorization Guideline

Guideline Name	Ocaliva (obeticholic acid)
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Ocaliva (obeticholic acid)
Primary Biliary Cholangitis Indicated for treatment of primary biliary cholangitis (PBC) in adult patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA. This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP). An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

2 . Criteria

Product Name: Ocaliva	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary biliary cholangitis (also known as primary biliary cirrhosis)

AND

2 - One of the following:

2.1 Both of the following:

- Patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) [1, A]
- Used in combination with ursodeoxycholic acid (UDCA)

OR

2.2 History of contraindication or intolerance to ursodeoxycholic acid (UDCA) [B]

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist

AND

4 - Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy) [3, C]

AND

5 - Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) [3, C]

Product Name: Ocaliva	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., laboratory values) documenting a reduction in ALP level from pre-treatment baseline (i.e., prior obeticholic acid therapy) while on therapy</p> <p style="text-align: center;">AND</p> <p>2 - Patient does not have evidence of advanced cirrhosis (i.e. cirrhosis with current or prior evidence of hepatic decompensation including encephalopathy or coagulopathy) [3, C]</p> <p style="text-align: center;">AND</p> <p>3 - Patient does not have evidence of portal hypertension (e.g., ascites, gastroesophageal varices, persistent thrombocytopenia) [3, C]</p>	

3 . Endnotes

- A. The recommended starting dosage of Ocaliva is 5 mg orally once daily for the first 3 months in adult patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, who have not achieved an adequate biochemical response to an appropriate dosage of UDCA for at least 1 year or are intolerant to UDCA. After the first 3 months, for patients who have not achieved an adequate reduction in ALP and/or total bilirubin and who are tolerating Ocaliva, increase to a maximum dosage of 10 mg once daily [1].
- B. Obeticholic acid (OCA) was also studied as monotherapy in 60 patients with early disease stage PBC, wherein no UDCA use was allowed for at least 3 months before screening in a phase II trial. Additionally, a phase III trial included only 16 (7%) subjects treated with OCA monotherapy. In an analysis of a pooled dataset consisting of Phase 2 and Phase 3 trials, the responder rate for monotherapy at 3 months was 38%, which is similar to the 41% responder rate achieved for the combination therapy (OCA plus UDCA) [2].
- C. On 5/26/2021, the FDA issued a black box warning restricting the use of Ocaliva in patients having primary biliary cholangitis (PBC) with advanced cirrhosis of the liver because it can cause serious harm. Some PBC patients with cirrhosis who took Ocaliva,

especially those with evidence of advanced cirrhosis, developed liver failure, sometimes requiring liver transplant. In the five years since Ocaliva's accelerated approval, FDA identified 25 cases of serious liver injury leading to liver decompensation or liver failure associated with Ocaliva in PBC patients with cirrhosis, both in those without clinical signs of cirrhosis (compensated) or in those with clinical signs of cirrhosis (decompensated). Many of these PBC patients had advanced cirrhosis before starting Ocaliva [3].

4 . References

1. Ocaliva Prescribing Information. Intercept Pharmaceuticals, Inc. New York, NY. May 2021.
2. FDA Briefing Document (Obeticholic Acid): Gastrointestinal Drug Advisory Committee (GIDAC). Food and Drug Administration Web site. <https://www.fda.gov/media/97298/download>. Accessed September 2, 2021.
3. FDA Drug Safety Communication: FDA adds Boxed Warning to restrict use of Ocaliva (obeticholic acid) in primary biliary cholangitis (PBC) patients with advanced cirrhosis. Food and Drug Administration Web site. <https://www.fda.gov/drugs/drug-safety-and-availability/due-risk-serious-liver-injury-fda-restricts-use-ocaliva-obeticholic-acid-primary-biliary-cholangitis> Accessed September 2, 2021.

Prior Authorization Guideline

Guideline Name	Octreotide Products - PA, NF
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Guideline Note:

Effective Date:	6/15/2022
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1 . Indications

Drug Name: Sandostatin (octreotide acetate)

Acromegaly Indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. The goal is to achieve normalization of growth hormone and IGF-I (somatomedin C) levels. In patients with acromegaly, Sandostatin reduces growth hormone to within normal ranges in 50% of patients and reduces IGF-I (somatomedin C) to within normal ranges in 50%-60% of patients. Since the effects of pituitary irradiation may not become maximal for several years, adjunctive therapy with Sandostatin to reduce blood levels of growth hormone and IGF-I (somatomedin C) offers potential benefit before the effects of irradiation are manifested. Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin; these trials were not optimally designed to detect such effects.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. Sandostatin studies were not designed to show an effect on the size, rate of growth or development of metastases.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for the treatment of the profuse watery diarrhea associated with VIP-

secreting tumors. Sandostatin studies were not designed to show an effect on the size, rate of growth or development of metastases.

Drug Name: Sandostatin LAR Depot (octreotide acetate)

General Indicated in patients in whom initial treatment with Sandostatin Injection has been shown to be effective and tolerated.

Acromegaly Indicated for long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option. The goal of treatment in acromegaly is to reduce GH and IGF-1 levels to normal.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for long-term treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitation of Use: The effect of Sandostatin LAR on tumor size, rate of growth and development of metastases, has not been determined.

Drug Name: Bynfezia (octreotide acetate injection)

Acromegaly Indicated for reduction of growth hormone (GH) and insulin-like growth factor 1 (IGF-1) [somatomedin C] in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. Limitation of Use: In patients with acromegaly, the effect of Bynfezia Pen on improvement in clinical signs and symptoms, reduction in tumor size and rate of growth, has not been determined.

Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing Indicated for treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients. Limitation of Use: In patients with carcinoid syndrome, the effect of Bynfezia Pen on size, rate of growth and development of metastases, has not been determined.

Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea Indicated for treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients. Limitation of Use: In patients with VIPomas, the effect of Bynfezia Pen on size, rate of growth and development of metastases, has not been determined.

Drug Name: Mycapssa (octreotide capsule, delayed release)

Acromegaly Indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

2 . Criteria

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of acromegaly</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Inadequate response to one of the following:</p> <ul style="list-style-type: none">• Surgery• Pituitary irradiation <p style="text-align: center;">OR</p> <p>2.2 Not a candidate for surgical resection or pituitary irradiation</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p>	

4.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

4.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of acromegaly</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Inadequate response to one of the following:</p> <ul style="list-style-type: none">• Surgery• Pituitary irradiation <p style="text-align: center;">OR</p> <p>2.2 Not a candidate for surgical resection or pituitary irradiation</p> <p style="text-align: center;">AND</p> <p>3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide</p>	

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)</p>	

Product Name: Brand Sandostatin, Bynfezia	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of acromegaly</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Inadequate response to one of the following:</p> <ul style="list-style-type: none"> • Surgery • Pituitary irradiation <p style="text-align: center;">OR</p> <p>2.2 Not a candidate for surgical resection or pituitary irradiation</p>	

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

Product Name: Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of acromegaly</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Inadequate response to one of the following:</p> <ul style="list-style-type: none">• Surgery• Pituitary irradiation <p style="text-align: center;">OR</p> <p>2.2 Not a candidate for surgical resection or pituitary irradiation</p>	

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)</p>	

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of an improvement in the number of diarrhea or flushing episodes

Product Name: Brand Sandostatin, Bynfezia

Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia

Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea

AND

2 - One of the following:

2.1 Patient has had a trial of short-acting generic octreotide and responded to and tolerated therapy (Applies to Sandostatin LAR only)

OR

2.2 Trial and failure, or intolerance to generic octreotide (Applies to Brand Sandostatin and Bynfezia only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of an improvement in the number of diarrhea episodes	

Product Name: Brand Sandostatin, Bynfezia	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea	

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic octreotide

3 . References

1. Sandostatin Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2021.
2. Sandostatin LAR Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2021.
3. Octreotide Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. May 2021.
4. Bynfezia Prescribing Information. Sun Pharmaceutical Industries Ltd. Gujarat, India. April 2020.
5. Mycapssa Prescribing Information. MW Encap Ltd. Scotland, UK. June 2020.

Odomzo (sonidegib)

Prior Authorization Guideline

Guideline Name	Odomzo (sonidegib)
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Guideline Note:

Effective Date:	3/1/2022
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1 . Indications

Drug Name: Odomzo (sonidegib)
Locally advanced basal cell carcinoma (BCC) Indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

2 . Criteria

Product Name: Odomzo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of locally advanced basal cell carcinoma [2]	

AND

2 - One of the following:

- Cancer has recurred following surgery or radiation therapy
- Patient is not a candidate for surgery or radiation therapy

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist [A]
- Oncologist

Product Name: Odomzo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Verified with consultant that other specialists such as Dermatologists may prescribe sonidegib in addition to Oncologists. [3]

4 . References

1. Odomzo Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. May 2019.

2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer. v.2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed August 13, 2021.
3. Per clinical consult with oncologist, February 24, 2011.

Olumiant (baricitinib)

Prior Authorization Guideline

Guideline Name	Olumiant (baricitinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Olumiant (baricitinib)
<p>Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers. Limitation of Use: Not recommended for use in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.</p> <p>Coronavirus Disease 2019 (COVID-19) Indicated for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).</p> <p>Alopecia Acreata (AA) Indicated for the treatment of adult patients with severe alopecia areata. Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.</p>

2 . Criteria

Product Name: Olumiant

Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

- methotrexate
- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - One of the following:

5.1 All of the following:

5.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab pegol)

- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

5.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

OR

5.2 For continuation of prior Olumiant therapy, defined as no more than a 45-day gap in therapy

AND

6 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**

Notes	<p>*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.</p> <p>**Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).</p>
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Product Name: Olumiant	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)**

Notes	**Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization, Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of COVID-19</p> <p style="text-align: center;">AND</p> <p>2 - Patient is hospitalized</p> <p style="text-align: center;">AND</p> <p>3 - Patient requires one of the following:</p> <ul style="list-style-type: none"> • Supplemental oxygen • Non-invasive mechanical ventilation • Invasive mechanical ventilation • Extracorporeal membrane oxygenation (ECMO) 	

Product Name: Olumiant	
Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of alopecia areata</p> <p style="text-align: center;">AND</p> <p>2 - Patient has at least 50% scalp hair loss [1, 4]</p> <p style="text-align: center;">AND</p> <p>3 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, tinea capitis, psoriasis) [4]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a dermatologist</p> <p style="text-align: center;">AND</p> <p>5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*</p>	
Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant

Diagnosis	Alopecia Areata
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*</p>	
Notes	*Olumiant may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . References

1. Olumiant Prescribing Information. Eli Lilly and Company. Indianapolis, IN. June 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res. 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. King B, Ohyama M, Kwon O, et al. Two phase 3 trials of baricitinib for alopecia areata. N Engl J Med 2022;386:1687-99.
5. Meah N, Wall D, York K, et al. The Alopecia Areata Consensus of Experts (ACE) study: results of an international expert opinion on treatments for alopecia areata. J Am Acad Dermatol. 2020;83(1):123-130.

Olysio (simeprevir)

Prior Authorization Guideline

Guideline Name	Olysio (simeprevir)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Olysio (simeprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1 or 4 – Olysio + Alfa Interferons + Ribavirin Treatment Regimen
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following: 1.1 Both of the following: <ul style="list-style-type: none">• Diagnosis of chronic hepatitis C genotype 1a infection• Patient does not have the NS3 Q80K polymorphism	

OR

1.2 Diagnosis of chronic hepatitis C genotype 1b infection

OR

1.3 Diagnosis of chronic hepatitis C genotype 4 infection

AND

2 - Patient has not experienced failure with a previous treatment regimen that includes Olysio or other HCV NS3/4A protease inhibitors [e.g., Incivek (telaprevir), Victrelis (boceprevir)]

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Used in combination with peginterferon alfa and ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Olysio therapy

Product Name: Olysio (simeprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1 - without Cirrhosis – Olysio + Sovaldi Treatment Regimen
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1	
AND	
2 - Patient is without cirrhosis	
AND	
3 - Used in combination with Sovaldi (sofosbuvir)	

AND

4 - Patient has not experienced failure with a previous treatment regimen that includes Olysio or other HCV NS3/4A protease inhibitors [e.g., Incivek (telaprevir), Victrelis (boceprevir)]

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Olysio therapy

Product Name: Olysio (simeprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1 - with Cirrhosis – Olysio + Sovaldi Treatment Regimen
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 1</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting that the patient has cirrhosis</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with Sovaldi (sofosbuvir)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious disease specialist • HIV specialist certified through the American Academy of HIV Medicine <p style="text-align: center;">AND</p> <p>5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)</p>	

AND

6 - Patient has not experienced failure with a previous treatment regimen that includes Olysio or other HCV NS3/4A protease inhibitors [e.g., Incivek (telaprevir), Victrelis (boceprevir)]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Olysio therapy

2 . References

1. Olysio Prescribing Information. Janssen Therapeutics, November 2017.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2017. <http://www.hcvguidelines.org/full-report-view>. Accessed January 15, 2018.

Prior Authorization Guideline

Guideline Name	Oncology Injectable
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Guideline Note:

Effective Date:	9/1/2023
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Note:

The purpose of this guideline is to establish policies and procedures on how to handle formulary injectable oncology drugs (Adcetris, Cymraza, Elzonris, Keytruda, Lartruvo, Opdivo, Portrazza, Rylaze, Tecentriq, and Yervoy) with a prior authorization requirement that do not have official criteria posted or available. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, non-formulary drugs, or drugs that are not reviewed for prior authorization by OptumRx.

1 . Criteria

Product Name: Adcetris, Blincyto, Cyramza, Elzonris, Erbitux, Keytruda, Opdivo, Portrazza, Rylaze, Tecentriq, Yervoy, Aliqopa	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria 1 - One of the following:	

1.1 Both of the following:

1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication

AND

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

AND

2 - Prescribed by or in consultation with an oncologist

Onfi (clobazam), Sympazan (clobazam)

Prior Authorization Guideline

Guideline Name	Onfi (clobazam), Sympazan (clobazam)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Onfi (clobazam) tablets and oral suspension, Sympazan (clobazam) oral film
Lennox-Gastaut syndrome (LGS) Indicated for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients 2 years of age or older.
Off Label Uses: Refractory Seizures There is some clinical evidence to support the use in refractory seizures. [5, 6]

2 . Criteria

Product Name: Brand Onfi, generic clobazam, or Sympazan	
Diagnosis	Seizures associated with Lennox-Gastaut Syndrome and Dravet Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - All of the following:

1.1 Diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS) [1]

AND

1.2 Used as adjunctive therapy [2, A]

AND

1.3 Patient is 2 years of age or older

AND

1.4 Prescribed by or in consultation with a neurologist

AND

1.5 Both of the following (for Brand Onfi and Sympazan ONLY):

1.5.1 Trial and failure, contraindication, or intolerance to generic clobazam

AND

1.5.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

OR

2 - All of the following: [4]

2.1 Diagnosis of seizures associated with Dravet syndrome (DS)

AND

2.2 Used in combination with Diacomit (stiripentol)

AND

2.3 Both of the following:

- Patient is 6 months of age or older
- Patient weighs greater than or equal to 7 kg

AND

2.4 Prescribed by or in consultation with a neurologist

AND

2.5 Both of the following (or Brand Onfi and Sympazan ONLY):

2.5.1 Trial and failure, contraindication, or intolerance to generic clobazam

AND

2.5.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Onfi, Sympazan	
Diagnosis	Refractory seizures [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following: [B, 5-6]</p> <p>1.1 Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs)</p> <p style="text-align: center;">AND</p> <p>1.2 Used as adjunctive therapy</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <p>2.1 Trial and failure, contraindication, or intolerance to generic clobazam</p> <p style="text-align: center;">AND</p> <p>2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:</p> <ul style="list-style-type: none"> • Allergic response or intolerance to one of the inactive ingredients of the generic drug • Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium) <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Generic clobazam	
Diagnosis	Refractory seizures [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following: [B, 5-6]</p> <p>1.1 Diagnosis of refractory seizures (inadequate response to at least two antiepileptic drugs)</p> <p style="text-align: center;">AND</p> <p>1.2 Used as adjunctive therapy</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Brand Onfi, generic clobazam, or Sympazan	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p>	

2 - Both of the following (or Brand Onfi and Sympazan ONLY):

2.1 Trial and failure, contraindication, or intolerance to generic clobazam

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . Endnotes

- A. Clobazam is approved for adjunctive therapy of LGS. In the pivotal trials, study participants were receiving from 1 to 3 concomitant antiepileptic drugs at stable doses for at least 4 weeks [1, 2]
- B. Refractory status epilepticus is when seizures are not controlled after the administration of two antiseizure medications. [5]

4 . References

1. Onfi Prescribing Information. Lundbeck. Deerfield, IL. January 2023.
2. Ng Y-T, Conry JA, Drummond R, et al. Randomized, phase III study results of clobazam in Lennox-Gastaut syndrome. *Neurology*. 2011;77:1473-81.
3. Sympazan Prescribing Information. Aquestive Therapeutics. Warren, NJ. January 2023.
4. Diacomit Prescribing Information. Biocodex. Beauvais, France. July 2022.
5. Drislane, F. UptoDate. Refractory status epilepticus in adults. March 2023. Available at: https://www.uptodate.com/contents/refractory-status-epilepticus-in-adults?search=onfi&source=search_result&selectedTitle=3~17&usage_type=default&display_rank=3. Accessed April 18, 2023.
6. Epilepsy Foundation. Drug Resistant Epilepsy. Available at: <https://www.epilepsy.com/treatment/medicines/drug-resistant-epilepsy>. Accessed April 18, 2023.

Onureg (azacitidine)

Prior Authorization Guideline

Guideline Name	Onureg (azacitidine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Onureg (azacitidine)
Acute Myeloid Leukemia (AML) Indicated for continued treatment of adult patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.

2 . Criteria

Product Name: Onureg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.) [2]

AND

3 - Patient has achieved one of the following:

- first complete remission (CR)
- complete remission with incomplete blood count recovery (CRi)

AND

4 - Patient is not able to complete intensive curative therapy

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Onureg	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Onureg prescribing information. Celgene Corporation. Summit, NJ. September 2020.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v4.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed October 7,2020.

Prior Authorization Guideline

Guideline Name	Opdualag (nivolumab and relatlimab-rmbw)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Opdualag (nivolumab and relatlimab-rmbw)
Metastatic Melanoma Indicated for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

2 . Criteria

Product Name: Opdualag	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following diagnoses:	

- Unresectable melanoma
- Metastatic melanoma

AND

2 - Both of the following:

- Patient is 12 years of age or older
- Patient weighs at least 40 kg (88 lbs)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Opdualag	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Opdualag Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. March 2022.

Prior Authorization Guideline

Guideline Name	Opioid Intensive Case Management
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Guideline Note:

Effective Date:	3/1/2022
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1 . Criteria

Product Name: Opioid Program with Drug Lock-in	
Diagnosis	Cancer, hospice, palliative care, end of life care, long-term care, sickle cell anemia
Guideline Type	Administrative
Approval Criteria 1 - One of the following: 1.1 Member has a diagnosis of cancer OR 1.2 Member is enrolled in hospice	

OR

1.3 Member is receiving palliative care

OR

1.4 Member is receiving end of life care

OR

1.5 Member is a resident of a long-term care facility (LTC)

OR

1.6 Member has diagnosis of sickle cell anemia

Notes	Term the ICM POS edit (negative authorization) by changing the Thru Date to one day before the requested start date and cancel the case as Review Approval – Formulary Accessible.
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Product Name: Opioid Program with Drug Lock-in	
Diagnosis	Other
Guideline Type	Administrative
Approval Criteria 1 - Opioid prescriber can attest to medical necessity by addressing all the following: 1.1 The prescriber maintains and provides chart documentation of the patient's evaluation, including all the following: <ul style="list-style-type: none">• An appropriate patient medical history and physical examination• A description of the nature and intensity of the pain• Documentation of ongoing, periodic review of the course of opioid therapy	

- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

AND

1.2 Provider attests to both of the following:

- In his/her clinical judgment the requested drug(s) is medically required
- The restrictions imposed by the drug management program would be detrimental to the member's health or inappropriate

Notes	If approved, the drug-level POS edit will be lifted only for the drug requested. All other member-level POS edits will remain active. Approval Duration: For all overturned edit, end dates should be entered to extend until the end of the original POS edit restriction date
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Product Name: Opioid Program with Drug Lock-in	
Diagnosis	Natural disaster, short-term use, emergency room/urgent care
Approval Length	6 months or through date of negative auth, whichever is sooner
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Due to Natural disaster (Federally declared natural disaster) or drug shortage, access to restricted medication is unavailable</p> <p style="text-align: center;">OR</p> <p>1.2 Lock-in prescriber issues a prescription for short-term use of an additional opioid (any changes to long-term use or restricted opioid must be re-evaluated through case managed through the Clinical Engagement Services Call Center)</p>	

OR

1.3 Request due to an emergency room or urgent care visit

Prior Authorization Guideline

Guideline Name	Opioid Quantity Limit Overrides
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Diagnosis	For Malignant Cancer Pain
Approval Length	5 year(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:</p> <p style="padding-left: 20px;">1.1 Diagnosis of malignant (cancer) pain*</p>	
Notes	<p>Authorization will be issued for long-term therapy.</p> <p>*For oral fentanyl products, please refer to the drug-specific quantity limit override criteria in the "Oral Fentanyl Products" guideline.</p>



Diagnosis	For Non-Malignant Pain
Approval Length	1 year(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:</p> <p>1.1 Prescribed by a pain specialist or by pain management consultation</p> <p style="text-align: center;">AND</p> <p>1.2 The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following:</p> <ul style="list-style-type: none"> • An appropriate patient medical history and physical examination • A description of the nature and intensity of the pain • Documentation of appropriate dose escalation • Documentation of ongoing, periodic review of the course of opioid therapy • An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function) • Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian 	

Prior Authorization Guideline

Guideline Name	Opioid Risk Management
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Guideline Note:

Effective Date:	11/1/2023
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1 . Criteria

Product Name: Short-Acting Opioids	
Diagnosis	Cancer or end-of-life care
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Diagnosis of cancer or end of life care</p>	
Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids

Diagnosis	Postoperative Pain Management
Approval Length	14 Day(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Medication is being used to treat postoperative pain</p> <p style="text-align: center;">AND</p> <p>2 - Medication is not being prescribed for pain related to a dental procedure</p> <p style="text-align: center;">AND</p> <p>3 - The dose being prescribed is the dose that the patient was stable on prior to discharge</p>	
Notes	*Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	All Other Diagnoses
Approval Length	6 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate</p> <p style="text-align: center;">AND</p>	

2 - Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed

AND

3 - Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists

Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) has verbally addressed criterion (2) and/or (3) with the patient.
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Product Name: Opioid Cough Medications	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older</p>	

Product Name: Opioid Cough Medications*	
Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - One of the following:</p>	

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes

*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acet

	aminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.
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Product Name: Long Acting Opioids: Nucynta ER	
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Diagnosis	Cancer or End-of-Life Care
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Approval Length	12 month(s)
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Guideline Type	Prior Authorization
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<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of cancer</p> <p style="text-align: center;">OR</p> <p>1.2 Patient is receiving opioids as part of end-of-life care</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication or intolerance to at least two of the following preferred products</p> <ul style="list-style-type: none"> • Hydromorphone ER • Morphine sulfate ER • Oxymorphone ER • Hysingla ER • Oxycontin • Xtampza ER 	
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Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 All of the following:</p> <p>1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic</p> <p style="text-align: center;">AND</p> <p>1.1.2 One of the following:</p> <p>1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]</p> <p style="text-align: center;">OR</p> <p>1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia</p> <p style="text-align: center;">AND</p> <p>1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8</p>	

weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER

<ul style="list-style-type: none"> • Morphine sulfate ER • Oxymorphone ER • Hysingla ER • Oxycontin • Xtampza ER 	
Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation has been provided addressing ALL of the following</p> <ul style="list-style-type: none"> • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10) • Rationale for not tapering and discontinuing • Patient has been screened for comorbid mental health • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose 	
Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the request

	ed drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation has been provided addressing ALL of the following:</p> <ul style="list-style-type: none"> • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose 	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/stren

	gth combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of cancer</p> <p style="text-align: center;">OR</p> <p>1.2 Patient is receiving opioids as part of end-of-life care</p>	

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is being treated for cancer related pain or pain associated with end-of-life</p>	
Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
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Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment</p> <p style="text-align: center;">AND</p> <p>2 - None of the following:</p> <ul style="list-style-type: none"> • For use as an as-needed PRN analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • For opioid dependence <p style="text-align: center;">AND</p> <p>3 - The patient is not receiving other long-acting opioids concurrently</p>	
Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)
- Rationale for not tapering and discontinuing opioid
- Patient has been screened for comorbid mental health conditions
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Total daily morphine equivalent dose

Notes	*Prior authorization may not apply depending on the plan. If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/str length combination up to the requested quantity and/or MME for transition to an alternative treatment.
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2 . References

1. Zohydro ER Prescribing Information.Currax Pharmaceuticals LLC. October 2019.

Opzelura (ruxolitinib)

Prior Authorization Guideline

Guideline Name	Opzelura (ruxolitinib)
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Guideline Note:

Effective Date:	12/1/2022
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1 . Indications

Drug Name: Opzelura (ruxolitinib)
<p>Atopic Dermatitis Indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Limitation of Use: Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.</p> <p>Nonsegmental Vitiligo Indicated for the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older. Limitation of Use: Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended.</p>

2 . Criteria

Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	12 weeks [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of mild to moderate atopic dermatitis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Allergist/Immunologist <p style="text-align: center;">AND</p> <p>4 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:</p> <ul style="list-style-type: none"> • Medium or higher potency topical corticosteroid • Elidel (pimecrolimus) cream* • Tacrolimus ointment • Eucrisa (crisaborole) ointment* <p style="text-align: center;">AND</p> <p>5 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)</p> <p style="text-align: center;">AND</p> <p>6 - Opzelura will only be used for short-term and/or non-continuous chronic treatment</p>	

Notes	*Product may require step therapy
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Product Name: Opzelura	
Diagnosis	Atopic Dermatitis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:</p> <ul style="list-style-type: none"> • Reduction in body surface area involvement from baseline • Reduction in pruritus severity from baseline • Improvement in quality of life from baseline <p style="text-align: center;">AND</p> <p>2 - Patient is not receiving Opzelura in combination with a potent immunosuppressant (e.g., azathioprine or cyclosporine)</p> <p style="text-align: center;">AND</p> <p>3 - Opzelura will only be used for short-term and/or non-continuous chronic treatment</p>	

Product Name: Opzelura	
Diagnosis	Nonsegmental Vitiligo
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of nonsegmental vitiligo

AND

2 - Skin involvement includes facial vitiligo

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Opzelura	
Diagnosis	Nonsegmental Vitiligo
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to therapy as evidenced by improvement in repigmentation	
AND	
2 - Prescriber has evaluated patient and recommends another course of treatment	

3 . Background

Clinical Practice Guidelines

Table 1. Relative potencies of topical corticosteroids [2]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
	Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment
Clocortolone pivalate		Cream	0.1
Desoximetasone		Cream	0.05
Fluocinolone acetonide		Cream, ointment	0.025
Flurandrenolide		Cream, ointment, lotion	0.05
Fluticasone propionate		Cream	0.05
Fluticasone propionate		Ointment	0.005

	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

- A. Opzelura should be discontinued when signs and symptoms (e.g., itch, rash, and redness) of atopic dermatitis resolve. If signs and symptoms do not improve within 8 weeks, patients should be reexamined by their healthcare provider.

5 . References

1. Opzelura Prescribing Information. Incyte Corp. Wilmington, DE. September 2021.

Prior Authorization Guideline

Guideline Name	Oral Fentanyl Products
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Abstral (fentanyl)
<p>Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, or at least 25 mcg of transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid medication daily for a week or longer. Patients must remain on around-the-clock opioids when taking Abstral. Limitations of Use: As a part of the TIRF REMS Access program, Abstral may be dispensed only to outpatients enrolled in the program. For inpatient administration of Abstral (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.</p>
Drug Name: Actiq (fentanyl citrate) oral transmucosal lozenge
<p>Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any</p>

dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain. Actiq is intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Actiq Q may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Fentora (fentanyl buccal tablet)

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg/hr of transdermal fentanyl, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Fentora may be dispensed only to outpatients enrolled in the program. For inpatient administration of Fentora (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Lazanda (fentanyl) nasal spray

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Lazanda may be dispensed only to outpatients enrolled in the program. For inpatient administration of Lazanda (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient enrollment is not required.

Drug Name: Subsys (fentanyl sublingual spray)

Breakthrough pain Indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys . This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain. Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, Subsys may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of Subsys, patient enrollment is not required.

2 . Criteria

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Lazanda*, or Subsys	
Approval Length	12
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For the management of breakthrough cancer pain [A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]</p> <ul style="list-style-type: none"> • Morphine sulfate at doses of greater than or equal to 60 mg/day • Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr • Oxycodone at a dose of greater than or equal to 30 mg/day • Oral hydromorphone at a dose of greater than or equal to 8 mg/day • Oral oxymorphone at a dose of greater than or equal to 25 mg/day 	

- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - History of failure or intolerance to generic fentanyl lozenge

AND

4 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

5 - Prescribed by or in consultation with one of the following:

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Notes

*Product may be excluded depending on the plan

Product Name: Generic fentanyl lozenge	
Approval Length	12
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For the management of breakthrough cancer pain [A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]</p>	

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr
- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

4 - Prescribed by or in consultation with one of the following:

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Generic fentanyl lozenge, Lazanda*, or Subsys

Approval Length	12
Guideline Type	Quantity Limit

Approval Criteria

1 - For the management of breakthrough cancer pain

AND

2 - Prescribed by or in consultation with one of the following:

- Pain specialist

- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

AND

3 - The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: [3]

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

Notes

*Product may be excluded depending on the plan.

3 . Endnotes

- A. Abstral, Actiq, Fentora, Lazanda, and Subsys are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain [1, 2, 5, 6]
- B. Abstral, Actiq, Fentora, Lazanda, and Subsys are only intended for patients who are opioid tolerant. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. [1, 2, 5, 6]

4 . References

1. Actiq Prescribing Information. Cephalon. North Wales, PA. December 2016.
2. Fentora Prescribing Information. Cephalon. North Wales, PA. December 2016.
3. American Academy of Pain Medicine. The use of opioids for the treatment of chronic pain (2013). Available at: <http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf>. Accessed October 17, 2018.
4. Abstral Prescribing Information. Sentyln Therapeutics, Inc. Solana Beach, CA. December 2016.

5. Lazanda Prescribing Information. West Therapeutic Development, LLC. May 2018.
6. Subsys Prescribing Information. INSYS Therapeutics, Inc. Chandler, AZ. December 2016.

Prior Authorization Guideline

Guideline Name	Orencia (abatacept)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Orencia (abatacept) IV and SC
<p>Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic disease-modifying antirheumatic drugs [DMARDs], Janus kinase [JAK] inhibitors) is not recommended.</p> <p>Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.</p> <p>Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.</p>
Drug Name: Orencia (abatacept) IV
<p>Prophylaxis for Acute Graft versus Host Disease (aGVHD) Indicated for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Limitations of Use: The concomitant use of Orencia with other potent immunosuppressants (e.g., biologic DMARDs, JAK inhibitors) is not recommended.</p>

2 . Criteria

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active rheumatoid arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none">• methotrexate• leflunomide• sulfasalazine <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*</p> <ul style="list-style-type: none">• Cimzia (certolizumab pegol)• Enbrel (etanercept)	

- Humira (adalimumab)
- Rinvoq (upadacitinib)
- Simponi (golimumab)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Orencia IV or Orencia SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

- leflunomide
- methotrexate

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Enbrel (etanercept)
- Humira (adalimumab)
- Xeljanz (tofacitinib)

OR

4.2 For continuation of prior Orenzia therapy, defined as no more than a 45-day gap in therapy

Notes

* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.

Product Name: Orenzia IV or Orenzia SC

Diagnosis

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length

12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis (PsA)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [5]:</p> <ul style="list-style-type: none"> • Actively inflamed joints • Dactylitis • Enthesitis • Axial disease • Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p>	

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Orenzia therapy, defined as no more than a 45-day gap in therapy

Product Name: Orenzia IV or Orenzia SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline 	

- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used for prophylaxis of acute graft versus host disease (aGVHD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor</p> <p style="text-align: center;">AND</p> <p>4 - Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT</p> <p style="text-align: center;">AND</p> <p>5 - Used in combination with both of the following:</p> <ul style="list-style-type: none"> • calcineurin inhibitor (e.g., cyclosporine, tacrolimus) • methotrexate 	

3 . References

1. Orencia prescribing information. Bristol-Myers Squibb Company. Princeton, NJ. December 2021.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
5. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.

Orgovyx (relugolix)

Prior Authorization Guideline

Guideline Name	Orgovyx (relugolix)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Orgovyx (relugolix)
Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

2 . Criteria

Product Name: Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of advanced prostate cancer	

AND

2 - Disease is one of the following:

- Evidence of biochemical or clinical relapse following local primary intervention with curative intent
- Newly diagnosed androgen-sensitive metastatic disease
- Advanced localized disease unlikely to be cured by local primary intervention with curative intent

AND

3 - Prescribed by or in consultation with one of the following:

- Urologist
- Oncologist

Product Name: Orgovyx	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	
AND	
2 - Documentation of serum testosterone level less than 50 ng/dL	

3 . References

1. Orgovyx Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. December 2020.

Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), Myfembree (relugolix, estradiol, and norethindrone acetate)

Prior Authorization Guideline

Guideline Name	Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules), Myfembree (relugolix, estradiol, and norethindrone acetate)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Oriahnn (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules)

Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids) Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Drug Name: Myfembree (relugolix, estradiol, and norethindrone acetate)

Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids) Indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Pain Associated With Endometriosis Indicated for the management of moderate to severe pain associated with endometriosis in premenopausal women. Limitations of Use: Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

2 . Criteria

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is premenopausal</p> <p style="text-align: center;">AND</p> <p>3 - One of the following: [3, 5-6]</p> <p> 3.1 History of inadequate control of bleeding following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:</p> <ul style="list-style-type: none">• Combination (estrogen/progestin) contraceptive• Progestins• Tranexamic acid <p style="text-align: center;">OR</p> <p> 3.2 Patient has had a previous interventional therapy to reduce bleeding [B]</p> <p style="text-align: center;">AND</p> <p>4 - Treatment duration of therapy has not exceeded a total of 24 months [C]</p>	

Product Name: Oriahnn, Myfembree	
Diagnosis	Heavy Menstrual Bleeding Associated With Uterine Leiomyomas (Fibroids)
Approval Length	12 months(s) [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has improvement in bleeding associated with uterine leiomyomas (fibroids) (e.g., significant/sustained reduction in menstrual blood loss per cycle, improved quality of life, etc.)</p> <p style="text-align: center;">AND</p> <p>2 - Treatment duration of therapy has not exceeded a total of 24 months [C]</p>	

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe pain associated with endometriosis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is premenopausal</p> <p style="text-align: center;">AND</p>	

3 - ONE of the following:

3.1 History of inadequate pain control response following a trial of 30 days, or history of intolerance or contraindication to one of the following:

- Danazol
- Combination (estrogen/progestin) contraceptive
- Progestins

OR

3.2 Patient has had surgical ablation to prevent recurrence

AND

4 - Treatment duration of Myfembree has not exceeded a total of 24 months [C, 2]

Product Name: Myfembree	
Diagnosis	Pain Associated With Endometriosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)	
AND	
2 - Treatment duration of Myfembree has not exceeded a total of 24 months [C, 2]	

3 . Endnotes

- A. Results of UF-EXTEND and LIBERTY Extension demonstrated that up to 12 months of elagolix or relugolix with addback therapy provided sustained efficacy in reducing menstrual blood loss with no new or unexpected adverse effects compared with results of the preceding 6-month UF-1, UF-2, LIBERTY 1, and LIBERTY 2 studies. [4, 7]
- B. Alternatives to surgery include oral contraceptives, progestins, tranexamic acid, and a variety of interventional therapies (e.g., uterine-artery embolization and magnetic resonance–guided focused ultrasonography) [3, 5-6]
- C. Use of Oriahnn and Myfembree should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. [1, 2]

4 . References

1. Oriahnn Prescribing Information. AbbVie Inc. North Chicago, IL. August 2021.
2. Myfembree Prescribing Information. Myovant Sciences, Inc. Brisbane, CA. August 2022.
3. Schlaff WD, Ackerman RT, Al-Hendy A, et al. Elagolix for Heavy Menstrual Bleeding in Women with Uterine Fibroids. *N Engl J Med.* 2020;382(4): 328-340.
4. Simon JA, Al-Hendy A, Archer DF, et al. Elagolix Treatment for Up to 12 Months in Women With Heavy Menstrual Bleeding and Uterine Leiomyomas. *Obstet Gynecol.* 2020;135(6):1313-1326.
5. De La Cruz MS, Buchanan EM. Uterine Fibroids: Diagnosis and Treatment. *Am Fam Physician.* 2017 Jan 15;95 (2): 100-107. Available by subscription at: <https://www.aafp.org/afp/2017/0115/p100.html>. Accessed June 8, 2021.
6. Stewart EA. Uterine Fibroids (Leiomyomas): Treatment Overview. UpToDate. Available by subscription at: <https://www.uptodate.com>. Accessed July 14, 2022.
7. Al-Hendy A, Lukes AS, Poindexter A, et al. LIBERTY: Long-term Extension Study Demonstrating One-year Efficacy and Safety of Relugolix Combination Therapy in Women with Symptomatic Uterine Fibroids. ASRM Scientific Congress & Expo. October 2020. Available at: <https://asrm.confex.com/asrm/2020/meetingapp.cgi/Paper/7846>. Accessed July 27, 2021.
8. Nezhat, C., Vang, N. et al. Optimal Management of Endometriosis and Pain. *Obstetrics & Gynecology*: October 2019 - Vol. 134, Issue 4, p 834-839. Available at <https://journals.lww.com/greenjournal/pages/articleviewer.aspx?year=2019&issue=10000&article=00025&type=Fulltext>. Accessed September 10, 2022.

Orilissa (elagolix)

Prior Authorization Guideline

Guideline Name	Orilissa (elagolix)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of moderate to severe pain associated with endometriosis AND 2 - One of the following: [2, 3]	

2.1 History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

- Combination (estrogen/progesterone) oral contraceptive
- Danazol
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

Product Name: Orilissa 150 mg	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has improvement in pain associated with endometriosis (e.g., improvement in dysmenorrhea and nonmenstrual pelvic pain)	
AND	
2 - Treatment duration of Orilissa has not exceeded a total of 24 months [1]	

Product Name: Orilissa 200 mg*	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderate to severe pain associated with endometriosis	

AND

2 - One of the following: [2, 3]

2.1 History of inadequate pain control response following a trial of at least 3 months, or history of intolerance or contraindication to one of the following:

- Combination (estrogen/progesterone) oral contraceptive
- Danazol
- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

AND

3 - Treatment duration of Orilissa has not exceeded a total of 6 months [1]

Notes

*NOTE: Orilissa 200 mg is used for a maximum of 6 months.

2 . Endnotes

- A. Orilissa Prescribing Information. AbbVie Inc. North Chicago, IL. July 2018.
- B. Taylor H, Giudice L, Lessey B, et al. Treatment of endometriosis-associated pain with Elagolix, an oral GnRH Antagonist. N Engl J Med 2017; 377:28-40.
- C. Armstrong C. ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. Am Fam Physician. 2011 Jan 1;83 (1): 84-85. Available by subscription at: <https://www.aafp.org/afp/2011/0101/p84.html>. Accessed August 15, 2018.

Prior Authorization Guideline

Guideline Name	Orkambi (lumacaftor/ivacaftor)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Orkambi (lumacaftor/ivacaftor)
Cystic fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 1 years and older who are homozygous for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Limitations of Use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

2 . Criteria

Product Name: Orkambi (100 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - Patient is 6 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of cystic fibrosis (CF) AND 2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility	

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) tablet, Orkambi (200 mg - 125 mg) tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)	

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of cystic fibrosis (CF)	

AND

2 - Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility

AND

3 - One of the following:

3.1 Patient is 1 through 5 years of age

OR

3.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

AND

4 - Prescribed by or in consultation with one of the following:

- Specialist affiliated with a cystic fibrosis care center
- Pulmonologist

Product Name: Orkambi (100 mg - 125 mg) granules packet, Orkambi (150 mg - 188 mg) granules packet, Orkambi (75 mg - 94 mg) granules packet

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

AND

2 - One of the following:

2.1 Patient is 1 through 5 years of age

OR

2.2 Both of the following:

- Patient is 6 years of age or greater
- Patient is unable to swallow oral tablets

3 . References

1. Orkambi Prescribing Information. Vertex Pharmaceuticals Incorporated. Boston, MA. September 2022.

Orserdu (elacestrant)

Prior Authorization Guideline

Guideline Name	Orserdu (elacestrant)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Orserdu (elacestrant)
Breast Cancer Indicated for the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

2 . Criteria

Product Name: Orserdu	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of breast cancer	

AND

2 - Disease is one of the following:

- Advanced
- Metastatic

AND

3 - Disease is estrogen receptor (ER)-positive

AND

4 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

5 - Presence of estrogen receptor (ESR1) mutation(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)] [A, 1, 3]

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Orserdu	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . Endnotes

- A. Per clinical consult, treatment can be with an aromatase inhibitor, with or without fulvestrant, with or without CD4/6 inhibitors, as not all patients are candidates for CD4/6 inhibitors [3]

4 . References

1. Orserdu Prescribing Information. Stemline Therapeutics, Inc., New York, NY. January 2023.
2. Clinicaltrials.gov. Phase 3 Trial of Elacestrant vs. Standard of Care for the Treatment of Patients With ER+/HER2- Advanced Breast Cancer (EMERALD). Available at <https://www.clinicaltrials.gov/ct2/results?cond=&term=nct03778931&cntry=&state=&city=&dist=>. Accessed March 7, 2023.
3. Clinical Consult with an oncologist. March 16, 2023.
4. National Comprehensive Cancer Network(NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. V3.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 16, 2023.

Otezla (apremilast)

Prior Authorization Guideline

Guideline Name	Otezla (apremilast)
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Guideline Note:

Effective Date:	4/13/2022
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1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis.
Plaque Psoriasis Indicated for the treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy.
Oral Ulcers Associated with Behçet's Disease Indicated for the treatment of adult patients with oral ulcers associated with Behçet's Disease.

2 . Criteria

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., improvement in number of swollen/tender joints, pain, or stiffness)	

Product Name: Otezla	
Diagnosis	Plaque psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of plaque psoriasis	

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Otezla	
Diagnosis	Plaque psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:	
<ul style="list-style-type: none">• Reduction the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Behçet's Disease	
AND	
2 - Patient has active oral ulcers	

Product Name: Otezla	
Diagnosis	Oral Ulcers Associated with Behçet's Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)</p>	

3 . References

1. Otezla Prescribing Information. Celgene Corp. Summit, NJ. December 2021.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

Prior Authorization Guideline

Guideline Name	Oxbryta (voxelotor) - PA, NF
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Oxbryta (voxelotor)
Sickle Cell Disease Indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older.

2 . Criteria

Product Name: Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of sickle cell disease	

AND

2 - Patient is 4 years of age and older

AND

3 - Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation [2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea [3, 4]

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist/Oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

Product Name: Oxbryta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., an increase in hemoglobin level of greater than or equal to 1 g/dL from baseline, decreased annualized incidence rate of VOCs)	

AND

2 - Documentation of hemoglobin level that does not exceed 10.5 g/dL

Product Name: Oxbryta

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of sickle cell disease

AND

2 - Patient is 4 years of age and older

AND

3 - Documentation of hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation [2]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea [3, 4]

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist/Oncologist
- Specialist with expertise in the diagnosis and management of sickle cell disease

3 . References

1. Oxbryta (voxelotor) [Prescribing Information]. South San Francisco, CA. Global Blood Therapeutics, Inc; October 2022.
2. Vichinsky E, Hoppe C, Ataga K et al. A Phase 3 Randomized Trial of Voxelotor in Sickle Cell Disease. *New England Journal of Medicine*. 2019;381(6):509-519. doi:10.1056/nejmoa1903212.
3. Evidence-Based Management of Sickle Cell Disease: Expert Panel Report, 2014. Nhlbi.nih.gov. https://www.nhlbi.nih.gov/sites/default/files/media/docs/sickle-cell-disease-report%20020816_0.pdf. Published 2014. Accessed December 1, 2021.
4. Brawley O, Cornelius L, Edwards L et al. National Institutes of Health Consensus Development Conference Statement: Hydroxyurea Treatment for Sickle Cell Disease. *Ann Intern Med*. 2008;148(12):932. doi:10.7326/0003-4819-148-12-200806170-00220.

Prior Authorization Guideline

Guideline Name	Oxervate (cenegermin-bkbj) - PA, QL
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Oxervate (cenegermin-bkbj)
Neurotrophic Keratitis (NK) Indicated for the treatment of neurotrophic keratitis (NK).

2 . Criteria

Product Name: Oxervate	
Approval Length	8 weeks*
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of neurotrophic keratitis	

AND

2 - Trial and failure or intolerance to at least one over-the-counter ocular lubricant used at an optimal dose and frequency for at least two weeks (e.g., artificial tears, lubricating gels/ointments, etc.) [3]

AND

3 - Prescribed by or in consultation with an ophthalmologist

Notes	*Initial authorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime.
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Product Name: Oxervate	
Approval Length	One 8-Week Approval*
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Provider attests patient is being treated for disease recurrence (e.g., new corneal damage following prior corneal healing)</p> <p>AND</p> <p>1.1.2 Provider attests patient has not experienced treatment failure (e.g., patient has not experienced corneal healing after a previous course of Oxervate)</p> <p>OR</p>	

1.2 Provider attests treatment is for an eye that has not previously been treated with Oxervate	
Notes	*Reauthorization maximum coverage is limited to one 8-week approval. Oxervate is hard-coded with a quantity limit of 112 mL per lifetime. Subsequent request will be denied for off-label

Product Name: Oxervate	
Guideline Type	Quantity Limit*
<p>Approval Criteria</p> <p>1 - Requests for additional quantity will not be approved</p>	
Notes	*Requests will be denied off-label.

3 . References

1. Oxervate Prescribing Information. Dompe U.S. Inc. Boston, MA. October 2019.
2. FDA Medical Review: Oxervate. Drugs at FDA Web site.
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/761094Orig1s000MedR.pdf.
 Accessed April 1, 2021.
3. Per clinical consult with ophthalmologist, December 12, 2018.

Palforzia [Peanut (Arachis hypogaea)]

Prior Authorization Guideline

Guideline Name	Palforzia [Peanut (Arachis hypogaea)]
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp]
Peanut Allergy Indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial Dose Escalation may be administered to patients aged 4 through 17 years. Up-Dosing and Maintenance may be continued in patients 4 years of age and older. Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

2 . Criteria

Product Name: Palforzia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis and clinical history of peanut allergy as documented by both of the following:

- A serum peanut-specific IgE level of greater than or equal to 0.35 kUA/L
- A mean wheal diameter that is at least 3mm larger than the negative control on skin-prick testing for peanut

AND

2 - One of the following:

2.1 Both of the following:

- Patient is 4 to 17 years of age
- Patient is in the initial dose escalation phase of therapy

OR

2.2 Both of the following:

- Patient is 4 years of age and older
- Patient is in the up-dosing or maintenance phase of therapy

AND

3 - Patient does not have any of the following:

- History of eosinophilic esophagitis (EoE) or eosinophilic gastrointestinal disease
- History of severe or life-threatening episode(s) of anaphylaxis or anaphylactic shock within the past 2 months
- Severe or poorly controlled asthma

AND

4 - Prescribed by or in consultation with an allergist/immunologist

Product Name: Palforzia	
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Prescribed by or in consultation with an allergist/immunologist</p>	

3 . References

1. Palforzia prescribing information. Aimmune Therapeutics, Inc. Brisbane, CA. January 2020.
2. The PALISADE Group of Clinical Investigators. AR101 Oral Immunotherapy for Peanut Allergy. N Engl J Med. 379(21):1991-2001.

Palynziq (pegvaliase-pqpz)

Prior Authorization Guideline

Guideline Name	Palynziq (pegvaliase-pqpz)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Palynziq (pegvaliase-pqpz)
Phenylketonuria (PKU) Indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

2 . Criteria

Product Name: Palynziq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of phenylketonuria (PKU)	

AND

2 - Patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management (e.g., phenylalanine restricted diet, Kuvan [sapropterin])

AND

3 - One of the following:

3.1 Patient has had a trial and failure or intolerance to Kuvan (sapropterin)

OR

3.2 Patient is not a candidate for Kuvan (sapropterin) therapy due to the presence of two null mutations in trans

AND

4 - Patient will have phenylalanine blood levels measured every 4 weeks until a maintenance dose is established and periodically thereafter [A]

Product Name: Palynziq	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has experienced an objective response to therapy, defined by one of the following [B, C]:	
1.1 At least a 20% reduction in blood phenylalanine concentrations from pre-treatment baseline	

OR

1.2 Blood phenylalanine concentrations less than or equal to 600 micromol/L

AND

2 - Patient will continue to have phenylalanine blood levels measured periodically during therapy [A]

3 . Endnotes

- A. Patients should have blood phenylalanine (Phe) concentrations measured every 4 weeks after initiation of Palynziq (pegvaliase-pqpz), until a maintenance dosage is established. Periodic monitoring should continue after a maintenance dose is established [1].
- B. Therapy should be discontinued in patients who do not achieve at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 micromol/L after 16 weeks of continuous treatment with the maximum dosage of 40 mg once daily. Based on the recommended dosing regimen, patients could be evaluated for discontinuation after 49 weeks of therapy. This would allow for induction, titration, maintenance on 20 mg for 24 weeks, and maintenance on 40mg for 16 weeks.
- C. The American College of Medical Genetics and Genomics guideline suggests blood Phe levels should be maintained in the range of 120–360 micromol/L for all patients [2].

4 . References

- 1. Palynziq prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. November 2020.
- 2. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. Genet Med. 2014 Feb;16(2):188-200.

Prior Authorization Guideline

Guideline Name	PCSK9 Inhibitors
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Repatha (evolocumab)
<p>Prevention of Cardiovascular Events Indicated in adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization.</p> <p>Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia) Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.</p> <p>Heterozygous Familial Hypercholesterolemia (HeFH) Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C</p> <p>Homozygous Familial Hypercholesterolemia Indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C</p>
Drug Name: Praluent (alirocumab)
<p>Prevention of Cardiovascular Events Indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.</p> <p>Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia)</p>

Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.

Homozygous Familial Hypercholesterolemia Indicated as an adjunct to other LDL-C lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Repatha, Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age)</p> <p style="text-align: center;">OR</p> <p>1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following**: [1, 2, 4]</p> <ul style="list-style-type: none"> • Acute coronary syndromes • History of myocardial infarction • Stable or unstable angina • Coronary or other arterial revascularization • Stroke • Transient ischemic attack 	

- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [1, 2, 4]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [H]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [H]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins as documented in medical records

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [4]

AND

3 - One of the following: [7-8, 16-17]

3.1 Both of the following:

3.1.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values within the last 120 days:

3.1.1.1 LDL-C greater than or equal to 100 mg/dl within the last 120 days without ASCVD with baseline LDL greater than or equal to 190mg/dl, on maximally tolerated statin

OR

3.1.1.2 Both of the following:

3.1.1.2.1 LDL-C greater than or equal to 70 mg/dl, on maximally tolerated statin therapy for secondary prevention

AND

3.1.1.2.2 Patient has “not high risk” ASCVD as defined by both of the following:

3.1.1.2.2.1 Patient has had one or more major ASCVD events^

AND

3.1.1.2.2.2 Patient has no more than one high-risk conditions^

OR

3.1.1.3 Both of the following:

3.1.1.3.1 LDL-C greater than or equal to 55 mg/dl, on maximally tolerated statin therapy for secondary prevention

AND

3.1.1.3.2 Patient has “very high risk” ASCVD as defined by one of the following:

3.1.1.3.2.1 Patient has had 2 or more major ASCVD events^

OR

3.1.1.3.2.2 Patient has had one major ASCVD event AND two or more high-risk conditions^

AND

3.1.2 One of the following: [F]

- Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]
- Patient has a history of contraindication, or intolerance to ezetimibe

- Provide rationale of why addition of ezetimibe is not expected to lower LDL to recommended goal on maximally tolerated statin therapy (i.e., mean % reduction in LDL-C per package insert for monotherapy ~18%, incremental reduction with combination therapy with statin ~25%)

OR

3.2 Both of the following:

3.2.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.2.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits or at therapeutic goal

Notes	**Criterion 1.2 should be used for: 1) patients with ASCVD and 2) the secondary prevention of cardiovascular events in patients with established cardiovascular disease (ASCVD). ^See background for definitions of major ASCVD event and high-risk conditions.
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Product Name: Repatha, Praluent	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose</p>	

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)

AND

2 - Documentation of a reduction in LDL-C levels while on Repatha or Praluent therapy

Product Name: Repatha, Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [16]</p> <p>1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)</p> <p>OR</p> <p>1.2 Untreated/pre-treatment LDL-C greater than 560 mg/dL</p> <p>OR</p> <p>1.3 Both of the following:</p> <p>1.3.1 Untreated LDL-C greater than 400 mg/dL</p>	

AND

1.3.2 One of the following:

1.3.2.1 Evidence of diagnosed familial hypercholesterolemia (FH) in one or both parents

OR

1.3.2.2 With xanthoma or aortic valve disease before 20 years of age

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Patient is 10 years of age or older

Product Name: Repatha, Praluent	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

2 - Documentation of LDL-C reduction while on Repatha or Praluent therapy

3 . Background

Clinical Practice Guidelines

Major ASCVD Events

- Recent ACS (within the past 12 months)
- History of MI (other than recent ACS event listed above)
- History of ischemic stroke
- Symptomatic PAD (history of claudication with ABI <0.85 or previous revascularization or amputation)

High-Risk Conditions

- Age greater than or equal to 65 years
- Heterozygous familial hypercholesterolemia
- History of prior coronary artery bypass surgery or percutaneous coronary intervention outside of the major ASCVD event(s)
- Diabetes
- Hypertension
- CKD (eGFR 15-59 mL/min/1.73 m²)

- Current smoking
- Persistently elevated LDL-C (LDL-C greater than or equal to 100 mg/dL despite maximally tolerated statin therapy and ezetimibe)
- History of congestive HF

4 . Endnotes

- A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [4]
- B. In the Praluent and Repatha pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-3]
- C. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). [5]
- D. Lipid specialists are physicians certified by the American Board of Clinical Lipidology (ABCL) or the Accreditation Council for Clinical Lipidology (ACCL)[14, 15]
- E. Per the 2018 ACC/AHA national treatment guidelines, it is reasonable to use the following as indicators of anticipated therapeutic response to the recommended intensity of statin therapy. Focus is on the intensity of the statin therapy. As an aid to monitoring:
a) High-intensity statin therapy generally results in an average LDL-C reduction of greater than or equal to 50% from the untreated baseline; b) Moderate-intensity statin therapy generally results in an average LDL-C reduction of 30 to 49% from the untreated baseline. [4]
- F. Per the 2022 ACC/AHA non-statin decision pathway update, for patients who are maximized on statin therapy and above goal with baseline LDL-C greater than or equal to 190 mg/dL, it is reasonable to consider the addition of either ezetimibe or a PCSK9 inhibitor based on considerations of the additional percent LDL-C reduction desired. Ezetimibe may be favored in patients who require < 25% additional lowering of LDL-C. [16] In patients with clinical ASCVD who are judged to be very high risk with LDL-C 55 mg/dL or higher and considered for PCSK9 inhibitor therapy, maximally tolerated LDL-C lowering therapy can include maximally tolerated statin therapy and either ezetimibe or PCSK9 inhibitor, depending on distance to goal. [16]
- G. FOURIER, a double blind, placebo controlled, RCT was the first completed cardiovascular outcomes trial for the PCSK9 inhibitors. The trial enrolled 27,564 high-risk patients with cardiovascular disease and LDL-C levels greater than or equal to 70 mg/dL while receiving optimized lipid-lowering therapy (99.7% of patients were receiving moderate- or high-intensity statins). The composite endpoint of CV death, myocardial infarction, stroke, hospitalization for unstable angina, and coronary revascularization occurred in 9.8% of evolocumab-treated patients vs. 11.3% of placebo-treated patients (treatment difference of 1.5%; HR 0.85; 95% CI, 0.79 to 0.92; p < 0.001) during a median follow-up period of 26 months. No benefit was identified in CV death or death from any cause. [19]

- H. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [4]

5 . References

1. Praluent Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. April 2021.
2. Repatha Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2021.
3. WHO Familial Hypercholesterolemia Consultation Group. Familial Hypercholesterolemia (FH): report of a second WHO consultation. Geneva: World Health Organization; 1999.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73:e285-e350.
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8. Per clinical drug consult with cardiologist. August 3, 2015.
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Pedmark (sodium thiosulfate injection, solution)

Prior Authorization Guideline

Guideline Name	Pedmark (sodium thiosulfate injection, solution)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Pedmark (sodium thiosulfate injection, solution)
Prophylaxis of Cisplatin-Induced Ototoxicity. Indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors. Limitations of Use: The safety and efficacy of Pedmark have not been established when administered following cisplatin infusions longer than 6 hours. Pedmark may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

2 . Criteria

Product Name: Pedmark	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of solid tumors

AND

2 - Disease is BOTH of the following:

- Localized
- Non-Metastatic

AND

3 - Used for the prevention of ototoxicity due to cisplatin-based chemotherapy

AND

4 - Patient is 1 month of age or older

AND

5 - Prescribed by or in consultation with an oncologist

3 . References

1. Pedmark Prescribing Information. Fennec Pharmaceuticals, Inc. Hoboken, NJ. September 2022.
2. Clinical Consult - Pediatric Hematology/Oncology specialist. November 15, 2022.

Prior Authorization Guideline

Guideline Name	Pemazyre (pemigatinib) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Pemazyre (pemigatinib)
<p>Cholangiocarcinoma Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).</p> <p>Myeloid/Lymphoid Neoplasms Indicated for the treatment of adults with relapsed or refractory myeloid/lymphoid neoplasms (MLNs) with fibroblast growth factor receptor 1 (FGFR1) rearrangement.</p>

2 . Criteria

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cholangiocarcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Unresectable locally advanced • Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]</p> <p style="text-align: center;">AND</p> <p>4 - Patient has been previously treated (e.g., chemotherapy)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • hepatologist • gastroenterologist • oncologist 	

Product Name: Pemazyre	
Diagnosis	Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Myeloid/Lymphoid Neoplasms (MLNs)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is relapsed or refractory</p> <p style="text-align: center;">AND</p> <p>3 - Disease has presence of fibroblast growth factor receptor 1 (FGFR1) rearrangement [B]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Pemazyre	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Pemazyre	
Diagnosis	Cholangiocarcinoma

Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of cholangiocarcinoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Unresectable locally advanced • Metastatic <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) confirming disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [A]</p> <p style="text-align: center;">AND</p> <p>4 - Patient has been previously treated (e.g., chemotherapy)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • hepatologist • gastroenterologist • oncologist 	

Product Name: Pemazyre	
Diagnosis	Myeloid/Lymphoid Neoplasms

Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Myeloid/Lymphoid Neoplasms (MLNs)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is relapsed or refractory</p> <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) confirming disease has presence of fibroblast growth factor receptor 1 (FGFR1) rearrangement [B]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a hematologist/oncologist</p>	

3 . Endnotes

- A. Per consultant feedback, rearrangement's are specific to FGFR2.
- B. An FDA-approved test for detection of FGFR1 rearrangement in patients with relapsed or refractory myeloid/lymphoid neoplasm for selecting patients for treatment with Pemazyre is not available. However, MLNs with FGFR1 rearrangement can be confirmed with cytogenetic evaluation. [1]

4 . References

- 1. Pemazyre Prescribing Information. Incyte Corporation. Wilmington, DE. August 2022.

Picato (ingenol mebutate)

Prior Authorization Guideline

Guideline Name	Picato (ingenol mebutate)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Picato	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria 1 - Trial and failure, intolerance or contraindication to generic fluorouracil or generic imiquimod	

Prior Authorization Guideline

Guideline Name	Piqray (alpelisib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Piqray (alpelisib)
Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.

2 . Criteria

Product Name: Piqray	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of advanced or metastatic breast cancer

AND

2 - Disease is hormone receptor (HR)-positive

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-negative

AND

4 - Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Patient is one of the following:

- Postmenopausal woman
- Male

AND

6 - Used in combination with fulvestrant

AND

7 - Disease has progressed on or after an endocrine-based regimen

Product Name: Piqray

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Piqray Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2022.

Pomalyst (pomalidomide)

Prior Authorization Guideline

Guideline Name	Pomalyst (pomalidomide)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Pomalyst (pomalidomide)
<p>Multiple myeloma Indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.</p> <p>Kaposi Sarcoma Indicated for the treatment of: 1) Adult patients with AIDS-related Kaposi sarcoma (KS) after failure of highly active antiretroviral therapy (HAART). 2) Kaposi sarcoma (KS) in adult patients who are HIV-negative. Note: this indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).</p>

2 . Criteria

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of multiple myeloma</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of AIDS-related Kaposi sarcoma</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 Diagnosis of Kaposi sarcoma</p> <p style="text-align: center;">AND</p> <p>1.2.2 Patient is HIV-negative</p>	

AND

2 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Pomalyst	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Pomalyst Prescribing Information, Celgene Corporation, Summit, NJ. December 2022.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 6, 2023.

Prior Authorization Guideline

Guideline Name	Prior Authorization Administrative Guideline
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: PA Admin Drugs	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Both of the following:</p> <p> 1.1.1 Prescribed medication is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p>	

1.1.2 Both of the following labeling requirements have been confirmed:

1.1.2.1 All components of the FDA approved indication are met (e.g., concomitant use, previous therapy requirements, age limitations, testing requirements, etc.)

AND

1.1.2.2 Prescribed medication will be used at a dose which is within FDA recommendations

OR

1.2 Meets the off-label administrative guideline criteria

Notes	This guideline should not be used to address step therapy.
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Procysbi (cysteamine bitartrate)

Prior Authorization Guideline

Guideline Name	Procysbi (cysteamine bitartrate)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Procysbi (cysteamine bitartrate)
Nephropathic cystinosis Indicated for the treatment of nephropathic cystinosis in adults and pediatric patients 1 year of age and older.

2 . Criteria

Product Name: Procysbi Capsules, Procysbi Granules	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of nephropathic cystinosis	

AND

2 - One of the following [A, 2, 3]:

2.1 Diagnosis is confirmed by elevated leukocyte cystine levels (LCL)

OR

2.2 Diagnosis is confirmed by genetic analysis of the CTNS gene

OR

2.3 Diagnosis is confirmed by demonstration of cysteine corneal crystals by slit lamp examination

AND

3 - Patient is 1 year of age or older

Product Name: Procysbi Capsules, Procysbi Granules	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., decrease in cystine levels in white blood cells)	

3 . Endnotes

- A. A definitive diagnosis can be verified by measuring leukocyte cystine levels or genetic analysis of the CTNS gene or demonstration of corneal crystals by slit lamp examination [2-3]

4 . References

1. Procysbi prescribing information. Horizon Pharma USA, Inc. Lake Forest, IL. May 2021.
2. Emma F, Nesterva G, Langman C, et al. Nephropathic cystinosis: an international consensus document. *Nephrol Dial Transplant* (2014) 29: iv87–iv94.
3. Wilmer MJ, Schoeber JP, van den Heuvel LP, Levchenko EN. Cystinosis: practical tools for diagnosis and treatment [educational review]. *Pediatric Nephrology* 2011; 26: 205-15.

Prior Authorization Guideline

Guideline Name	Prolia (denosumab)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Prolia (denosumab)
Treatment of postmenopausal women with osteoporosis at high risk for fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral, and hip fractures.
Treatment to increase bone mass in men with osteoporosis at high risk for fracture Indicated for treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
Treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer [A] Indicated as a treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer. In these patients Prolia also reduced the incidence of vertebral fractures. NOTE: The use of Prolia for the treatment of bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).
Treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for

breast cancer [B] Indicated as a treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer. NOTE: The use of Prolia for the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer should not be confused with the use of Xgeva (another injectable formulation of denosumab) for the prevention of skeletal-related events (SREs) in patients with bone metastases from solid tumors (including breast cancer and prostate cancer).

Treatment of Glucocorticoid-Induced Osteoporosis Indicated for the treatment of glucocorticoid-induced osteoporosis in men and women at high risk of fracture who are either initiating or continuing systemic glucocorticoids in a daily dosage equivalent to 7.5 mg or greater of prednisone and expected to remain on glucocorticoids for at least 6 months. High risk of fracture is defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Prolia	
Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of nonmetastatic prostate cancer</p> <p style="text-align: center;">AND</p> <p>2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]</p> <p>2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]</p> <p style="text-align: center;">OR</p>	

2.2 Bilateral orchiectomy (i.e., surgical castration)

AND

3 - One of the following:

3.1 Age greater than or equal to 70 years [11,C]

OR

3.2 Both of the following:

3.2.1 Age less than 70 years [11]

AND

3.2.2 One of the following:

3.2.2.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [11]

OR

3.2.2.2 History of one of the following resulting from minimal trauma: [9,11]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., zoledronic acid) [19]

Product Name: Prolia

Diagnosis	Bone loss in men receiving androgen deprivation therapy for nonmetastatic prostate cancer
Approval Length	12 months [D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]</p> <p>1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]</p> <p style="text-align: center;">OR</p> <p>1.2 Bilateral orchiectomy (i.e., surgical castration)</p> <p style="text-align: center;">AND</p> <p>2 - No evidence of metastases</p> <p style="text-align: center;">AND</p> <p>3 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)</p>	

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12,B]

AND

3 - One of the following:

3.1 Bone mineral density (BMD) scan T-score less than -1.0 (1.0 standard deviation or greater below the mean for young adults) [12,E]

OR

3.2 History of one of the following resulting from minimal trauma: [9]

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

4 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate) [20]

Product Name: Prolia	
Diagnosis	Bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer
Approval Length	12 months [D]

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)</p>	

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [5,17]</p> <p style="padding-left: 20px;">2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">OR</p> <p>2.2 Both of the following:</p>	

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Postmenopausal women with osteoporosis or osteopenia at a high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is a male with osteoporosis or osteopenia

AND

2 - One of the following: [16,17]

2.1 Bone mineral density (BMD) scan indicative of osteoporosis: T-score less than or equal to -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

2.2 Both of the following:

2.2.1 BMD scan indicative of osteopenia: T-score between -1.0 and -2.5 (BMD T-score greater than -2.5 and less than or equal to -1.0) in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions

- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

2.3 History of one of the following resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

AND

3 - Trial and failure, intolerance, or contraindication to one bisphosphonate (e.g., alendronate)

Product Name: Prolia	
Diagnosis	Increase bone mass in men at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects</p>	

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

2 - Patient is initiating or continuing on greater than or equal to 7.5 mg/day of prednisone (or its equivalent) and is expected to remain on glucocorticoid therapy for at least 6 months

AND

3 - One of the following: [F]

3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following:

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [G]

Product Name: Prolia	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.) without significant adverse effects	

3 . Definitions

Definition	Description
Bone mineral density (BMD) [3]	A risk factor for fractures. By DXA, BMD is expressed as the amount of mineralized tissue in the area scanned (g/cm(to the power of 2)); with some technologies, BMD is expressed as the amount per volume of bone (g/cm(to the power of 3)). Hip BMD by DXA is considered the best predictor of hip fracture; it appears to predict other types of fractures as well as measurements made at other skeletal sites. Spine BMD may be preferable to assess changes early in menopause and after bilateral ovariectomy.

Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density in the spine, hip, or wrist using radiation exposure about one tenth that of a standard chest x-ray. Central DXA (spine, hip) is the preferred measurement for definitive diagnosis and for monitoring the effects of therapy.
Fracture [3]	Breakage of a bone, either complete or incomplete. Most studies of osteoporosis focus on hip, vertebra and/or distal forearm fractures. Vertebral fractures include morphometric as well as clinical fractures.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
Peripheral DXA [3]	A DXA test used to assess bone density in the forearm, finger and heel.
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess bone density; reflects three-dimensional bone mineral density. Usually used to assess the lumbar spine, but has been adapted for other skeletal sites. It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT).
Quantitative ultrasound densitometry (QUS) [3]	A diagnostic test used to assess bone density at the calcaneus or patella. Ultrasound measurements correlate only modestly with other assessments of bone density in the same patient, yet some prospective studies indicate that ultrasound may predict fractures as well as other measures of bone density.
Remodeling [3]	The ongoing dual processes of bone formation and bone resorption after cessation of growth.
Resorption [3]	The loss of substance (in this case, bone) through physiological or pathological means.
Risk factors [3]	For osteoporotic fractures, includes low BMD, parental history of hip fracture, low body weight, previous fracture, smoking, excess alcohol intake, glucocorticoid use, secondary osteoporosis (e.g., rheumatoid arthritis) and history of falls. These readily accessible and commonplace factors are associated with the risk of hip fracture and, in most cases, with that of vertebral and other types of fracture as well.

Severe or “established” osteoporosis [3]	Osteoporosis characterized by bone density that is 2.5 standard deviations or more below the young normal mean (T-score at or below -2.5), accompanied by the occurrence of at least one fragility-related fracture.
T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.
Z-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for persons of the same age and sex.

4 . Endnotes

- A. Androgen deprivation therapy (ADT) is commonly used in the treatment of prostate cancer. ADT can be accomplished using luteinizing hormone-releasing hormone (LHRH) agonists (medical castration), also known as gonadotropin releasing hormone (GnRH) agonists, or bilateral orchiectomy (surgical castration), which are equally effective. [13] Examples of LHRH agonists include Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin).
- B. Aromatase inhibitors (AIs) include selective, nonsteroidal AIs (Arimidex [anastrozole] and Femara [letrozole]) and steroidal AIs (Aromasin [exemestane]).
- C. Meta-analyses have shown that advancing age increases fracture risk beyond that predicted by age related loss of BMD. Although typical changes in BMD would predict a 4-fold increase in fracture risk from ages 50 to 90 years, fracture risk actually increases 30-fold. Estimated fracture rates using FRAX calculations reflect a strong influence of older age on risk for clinical fracture. When clinical factors were used without BMD in one cross-sectional study, FRAX estimated that 76.6% of men in their 70s and virtually all men 80 years old or older exceeded the NOF recommended risk threshold for drug therapy. [14]
- D. Most men run a 2-year course of androgen deprivation therapy while most women receive treatment with aromatase inhibitors for about 5 years. A one year treatment authorization is reasonable. [15]
- E. Owing to the rate of bone loss associated with breast cancer treatments (i.e., aromatase inhibitors), and uncertainties about the interaction between aromatase inhibitor use and BMD for fracture risk, the threshold for intervention has been set at a higher level than that generally recommended for postmenopausal osteoporosis. [8]
- F. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoporosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, or (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively. [18]
- G. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticoid-induced osteoporosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

5 . References

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Prior Authorization Guideline

Guideline Name	Promacta (eltrombopag)
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Promacta (eltrombopag)
<p>Treatment of Thrombocytopenia in Patients with Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.</p> <p>Treatment of Thrombocytopenia in Patients with Hepatitis C Infection Indicated for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. Promacta should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. Limitations of use: • Safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of chronic hepatitis C infection.</p> <p>Treatment of Severe Aplastic Anemia Indicated in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. Indicated for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.</p>

2 . Criteria

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none">• Persistent ITP• Chronic ITP• Relapsed/refractory ITP [8] <p style="text-align: center;">AND</p> <p>2 - Baseline platelet count is less than 30,000/mcL [2, 3, 8]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to one of the following: [2, 3, 8]</p> <ul style="list-style-type: none">• Corticosteroids• Immunoglobulins• Splenectomy <p style="text-align: center;">AND</p> <p>4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding</p>	

Product Name: Promacta	
Diagnosis	First-Line for Severe Aplastic Anemia
Approval Length	6 Months [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of severe aplastic anemia</p> <p style="text-align: center;">AND</p> <p>2 - Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy with any equine antithymocyte globulin plus cyclosporine, alemtuzumab, or high dose cyclophosphamide) [1]</p> <p style="text-align: center;">AND</p> <p>3 - Patient meets at least TWO of the following [9, 10]:</p> <ul style="list-style-type: none"> • Absolute neutrophil count < 500/mcL • Platelet count < 20,000/mcL • Absolute reticulocyte count < 60,000/mcL 	

AND

4 - Used in combination with standard immunosuppressive therapy (e.g., Atgam [antithymocyte globulin equine] and cyclosporine) [1]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Promacta

Diagnosis	Refractory Severe Aplastic Anemia
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Approval Length	16 weeks [B]
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of refractory severe aplastic anemia

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy with antithymocyte globulin (ATG) and cyclosporine [5-7]

AND

3 - Patient has thrombocytopenia defined as platelet count less than 30,000/mcL

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Promacta	
Diagnosis	Refractory Severe Aplastic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to Promacta therapy as evidenced by an increase in platelet count</p>	

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Planning to initiate and maintain interferon-based treatment [1]</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Currently receiving interferon-based treatment</p> <p style="text-align: center;">AND</p>	

3 - Prescribed by or in consultation with one of the following:

- Hematologist/oncologist
- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 For patients that started treatment with Promacta prior to initiation of treatment with interferon, Promacta will be approved when both of the following criteria are met:</p> <p>1.1.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C [1]</p> <p style="text-align: center;">AND</p> <p>1.1.2 Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with Promacta treatment by week 9 [C]</p> <p style="text-align: center;">OR</p> <p>1.2 For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion:</p> <p>1.2.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C</p>	

3 . Endnotes

- A. The prescribing information states that the total duration of Promacta treatment for first-line severe aplastic anemia is 6 months. [1]
- B. In patients with severe aplastic anemia, hematologic response requires dose titration, generally up to 150 mg, and may take up to 16 weeks after starting Promacta. The dose should be adjusted every 2 weeks as necessary to achieve the target platelet count greater than or equal to $50 \times 10^9/L$. If no hematologic response has occurred after 16 weeks of therapy with Promacta, therapy should be discontinued. [1]
- C. Promacta was studied in two phase 3 trials for chronic hepatitis C-associated thrombocytopenia in two periods. Patients received Promacta in the first period for a maximum of 9 weeks in order to achieve a pre-specified threshold platelet count (greater than or equal to $90 \times 10^9/L$ for Trial 1 and greater than or equal to $100 \times 10^9/L$ for Trial 2); if the pre-specified threshold platelet count was reached, initiation of antiviral therapy in combination with interferon and ribavirin was administered for up to 48 weeks in the second period. The lowest dose of Promacta should be used to achieve and maintain a platelet count necessary to initiate and maintain interferon-based therapy. Dose adjustments are based upon the platelet count response. [1]

4 . References

1. Promacta Prescribing Information. Novartis Pharmaceuticals Corp. East Hanover, NJ. October 2021.
2. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: <https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for>. Accessed January 15, 2021.
3. Bussel JB, Cheng G, Saleh MN, et al. Eltrombopag for the treatment of chronic idiopathic thrombocytopenic purpura. *New Engl J Med*. 2007;357(22):2237-47.
4. Saleh MN, Bussel JB, Cheng G, et al. Safety and efficacy of eltrombopag for treatment of chronic immune thrombocytopenia: results of the long-term, open-label EXTEND study. 2013;121:537-45.
5. Promacta product dossier. GlaxoSmithKline. Research Triangle Park, NC. 2013.
6. Desmond R, Townsley DM, Dumitriu B, et al. Eltrombopag restores trilineage hematopoiesis in refractory severe aplastic anemia that can be sustained on discontinuation of drug. *Blood*. 2014;123(12):1818-25.
7. Marsh JC, Ball SE, Cavenagh J, et al. Guidelines for the diagnosis and management of aplastic anemia. *Br J Haematol*. 2009;147(1):43-70.
8. Per clinical consult with hematologist/oncologist. June 20, 2018.
9. Townsley DM, Scheinberg P, Winkler T, et al. Eltrombopag added to standard immunosuppression for aplastic anemia: Supplementary appendix. *N Engl J Med* 2017;376:1540-50.
10. Per clinical consult with hematologist/oncologist. January 24, 2019.

Prior Authorization Guideline

Guideline Name	Proton Pump Inhibitors
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Guideline Note:

Effective Date:	2/15/2023
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1 . Criteria

Product Name: Generic rabeprazole tablets, Generic esomeprazole capsules, Generic esomeprazole suspension packet, Brand Nexium suspension packet, Generic lansoprazole capsules, Generic omeprazole capsules, Generic pantoprazole tablets	
Diagnosis	Twice-daily (BID) PPI Therapy***
Guideline Type	Quantity Limit
Approval Criteria 1 - One of the following: 1.1 Trial and inadequate response to once daily PPI regimen OR 1.2 A once daily PPI regimen is not appropriate to treat the patient's condition	

AND

2 - Requested dose does not exceed maximum dose range found in labeling or supported one of the following off label compendia for the requested product[^]:

- American Hospital Formulary Service Drug Information
- Micromedex Drug System
- Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Authorization of therapy will be issued for 12 months for all diagnoses, except for H. pylori eradication. For H. pylori eradication, authorization will be issued for 14 days. ***Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline. [^] Support found in labeling or compendia should be evaluated regardless of indication.
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2 . Background

Clinical Practice Guidelines

BID Max Range Dosing Table [1-4]

***Intent of table below is to provide a quick reference for BID dosing range listed by requested product. If the requested dose exceeds max dose listed below, PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 8/3/22]**

DRUG	DOSE RANGE
Aciphex (rabeprazole)	20 to 60 mg BID
Dexilant (dexlansoprazole)	30 mg BID

Esomeprazole strontium	49.3 mg BID (Max = 240 mg/day)
Nexium (esomeprazole)	20 to 40 mg BID (Max = 240 mg/day)
Prevacid (lansoprazole)	30 to 90 mg BID
Prilosec (omeprazole)	20 to 40 mg BID (Max = 360 mg/day; divide doses above 80mg)
Protonix (pantoprazole)	40 to 80 mg BID (Max = 240 mg/day)
Zegerid (omeprazole/ sodium bicarbonate)	No BID support found at time of last annual review

3 . References

1. Frazzoni M, Manno M, De Micheli E, Savarino V. Intra-oesophageal acid suppression in complicated gastro-oesophageal reflux disease: esomeprazole versus lansoprazole. *Dig Liver Dis.* 2006;38(2):85-90.
2. Huaiyuan G, Ma H, Wang J. Proton pump inhibitor therapy for the treatment of laryngopharyngeal reflux: a meta-analysis of randomized controlled trials. *J Clin Gastroenterol.* 2016;50(4):295-300.
3. Micromedex solutions Web site. <http://www.micromedexsolutions.com/home/dispatch>. Accessed August 19, 2020.
4. Rees JRE, Lao-Sirieix P, Wong A, Fitzgerald RC. Treatment for Barrett's oesophagus. *Cochrane Database of Syst Rev.* 2010;1. Art. No.: CD004060. doi:10.1002/14651858.CD004060.pub2.

Prior Authorization Guideline

Guideline Name	Pulmonary Arterial Hypertension Agents
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

<p>Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension</p> <p>Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with New York Heart Association (NYHA) Functional Class II–III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).</p>
<p>Drug Name: Adempas (riociguat) Tablets</p> <p>Pulmonary Arterial Hypertension (PAH) Indicated for treatment of adults with PAH (WHO Group I) to improve exercise capacity, WHO Functional Class, and to delay clinical worsening. Efficacy was shown in patients on riociguat monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO Functional Class II to III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).</p> <p>Chronic-Thromboembolic Pulmonary Hypertension (CTEPH) Indicated for treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH), (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO Functional Class.</p>
<p>Drug Name: Flolan (epoprostenol sodium) Injection</p>

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly (97%) patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (49%) or PAH associated with connective tissue diseases (51%).

Drug Name: Letairis (ambrisentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to 1) improve exercise ability and delay clinical worsening and 2) in combination with tadalafil to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (60%) or PAH associated with connective tissue diseases (34%).

Drug Name: Liqrev (sildenafil) suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical worsening.

Drug Name: Opsumit (macitentan) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to reduce the risks of disease progression and hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

Drug Name: Orenitram (treprostinil) Tablets

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).

Drug Name: Remodulin (treprostinil sodium) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%). Indicated to diminish the rate of clinical deterioration in patients with PAH requiring transition from epoprostenol. Consider the risks and benefits of each drug prior to transition.

Drug Name: Revatio (sildenafil) Injection, Tablets, Oral Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I): 1) In adults to improve exercise ability and delay clinical worsening. 2) in pediatric patients 1 to 17 years old to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise.

Drug Name: Tracleer (bosentan) Tablets, Tablets for Suspension

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I): 1) In adults to improve exercise ability and to decrease clinical worsening. Studies establishing effectiveness included predominantly patients with WHO Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (60%), PAH associated with connective tissue diseases (21%), and PAH associated with congenital heart disease with left-to right shunts (18%). 2) In pediatric patients aged 3 years and older with idiopathic or congenital PAH to improve pulmonary vascular resistance (PVR), which is expected to result in an improvement in exercise ability.

Drug Name: Tyvaso (treprostinil) Inhalation Solution, Tyvaso (treprostinil) DPI Inhalation Powder

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities. While there are long-term data on use of treprostinil by other routes of administration, nearly all controlled clinical experience with inhaled treprostinil has been on a background of bosentan (an endothelin receptor antagonist) or sildenafil (a phosphodiesterase type 5 inhibitor). The controlled clinical experience was limited to 12 weeks in duration.

Pulmonary Hypertension Associated with Interstitial Lung Disease (ILD) Indicated for the treatment of pulmonary hypertension associated with ILD (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

Drug Name: Veletri (epoprostenol) Injection

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise capacity. Studies establishing effectiveness included predominantly patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH or PAH associated with connective tissue diseases.

Drug Name: Ventavis (iloprost) Inhalation Solution

Pulmonary Arterial Hypertension (PAH) Indicated for the treatment of PAH (WHO Group I) to improve a composite endpoint consisting of exercise tolerance, symptoms (NYHA Class),

and lack of deterioration. Studies establishing effectiveness included predominately patients with NYHA Functional Class III-IV symptoms and etiologies of idiopathic or heritable PAH (65%) or PAH associated with connective tissue diseases (23%).

Drug Name: Uptravi (selexipag) Tablets and Injection

Pulmonary Arterial Hypertension Indicated for the treatment of PAH (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Patients had idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), PAH associated with congenital heart disease with repaired shunts (10%).

2 . Criteria

Product Name: Generic Alyq tablet, Generic tadalafil tablet, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Generic treprostinil injection, Generic sildenafil tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution

Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Tadliq oral suspension	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pulmonary arterial hypertension	
AND	
2 - Pulmonary arterial hypertension is symptomatic	
AND	
3 - One of the following:	

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic tadalafil

Product Name: Brand Letairis tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pulmonary arterial hypertension	
AND	
2 - Pulmonary arterial hypertension is symptomatic	

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic ambrisentan

Product Name: Brand Remodulin injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pulmonary arterial hypertension	

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic treprostinil

Product Name: Brand Revatio tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic sildenafil tablet

Product Name: Brand Tracleer tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - Trial and failure or intolerance to generic bosentan tablet

Product Name: Brand Revatio injection or Generic sildenafil injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of pulmonary arterial hypertension</p> <p style="text-align: center;">AND</p> <p>2 - Pulmonary arterial hypertension is symptomatic</p> <p style="text-align: center;">AND</p> <p>3 - One of the following</p> <p style="padding-left: 20px;">3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Pulmonologist • Cardiologist <p style="text-align: center;">AND</p> <p>5 - Patient is unable to take oral medications [2]</p> <p style="text-align: center;">AND</p>	

6 - For Brand Revatio injection, trial and failure or intolerance to generic sildenafil injection

Product Name: Liqrev, Brand Revatio oral suspension or Generic sildenafil oral suspension

Diagnosis	Pulmonary Arterial Hypertension
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Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of pulmonary arterial hypertension

AND

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

5 - For brand Revatio oral suspension, trial and failure, or intolerance to both of the following:

- Generic sildenafil tablets
- Generic sildenafil oral suspension

AND

6 - For Liquev, trial and failure or intolerance to generic sildenafil suspension

Product Name: Adempas tablet	
Diagnosis	Chronic Thromboembolic Pulmonary Hypertension (CTEPH)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)</p> <p>AND</p> <p>1.1.2 CTEPH is symptomatic</p> <p>OR</p> <p>1.2 Patient is currently on any therapy for the diagnosis of CTEPH</p>	

AND

2 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Tyvaso inhalation solution, Tyvaso Refill inhalation solution, or Tyvaso Start inhalation solution, Tyvaso DPI

Diagnosis	Pulmonary Hypertension associated with Interstitial Lung Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pulmonary hypertension associated with interstitial lung disease

AND

2 - Diagnosis of pulmonary hypertension associated with interstitial lung disease was confirmed by diagnostic test(s) (e.g., right heart catheterization, doppler echocardiogram, computerized tomography imaging)

AND

3 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Brand Adcirca tablet, Generic tadalafil tablet, Generic Alyq tablet, Tadliq oral suspension, Adempas tablet, Brand Flolan injection, Generic epoprostenol injection, Brand

Letairis tablet, Liquev, Generic ambrisentan tablet, Opsumit tablet, Orenitram tablet, Brand Remodulin injection, Generic treprostinil injection, Brand Revatio injection, Generic sildenafil injection, Brand Revatio tablet, Generic sildenafil tablet, Brand Revatio oral suspension, Generic sildenafil oral suspension, Brand Tracleer tablet, Generic bosentan tablet, Tracleer tablet for suspension, Tyvaso inhalation solution, Tyvaso Refill inhalation solution, Tyvaso Starter inhalation solution, Tyvaso DPI, Veletri injection, or Ventavis inhalation solution

Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For brand Revatio injection, brand Tracleer, brand Adcirca, brand Letairis, brand Remodulin injection, and brand Revatio tablet, trial and failure or intolerance to its generic counterpart

AND

3 - For brand Revatio oral suspension, trial and failure or intolerance to both of the following:

- Generic sildenafil tablets
- Generic sildenafil oral suspension

AND

4 - For Tadliq oral suspension, trial and failure or intolerance to generic tadalafil

AND

5 - For Liquev, trial and failure or intolerance to generic sildenafil suspension

Product Name: Uptravi tablet	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of pulmonary arterial hypertension</p> <p style="text-align: center;">AND</p> <p>2 - Pulmonary arterial hypertension is symptomatic</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p style="padding-left: 20px;">3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Both of the following:</p> <p style="padding-left: 40px;">4.1.1 Trial and failure, contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> • PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)] • Adempas (riociguat) 	

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

Product Name: Uptravi injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of pulmonary arterial hypertension	
AND	

2 - Pulmonary arterial hypertension is symptomatic

AND

3 - One of the following:

3.1 Diagnosis of pulmonary arterial hypertension was confirmed by right heart catheterization [A]

OR

3.2 Patient is currently on any therapy for the diagnosis of pulmonary arterial hypertension

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to one of the following:

- PDE-5 inhibitor [i.e., Adcirca (tadalafil), Revatio (sildenafil)]
- Adempas (riociguat)

AND

4.1.2 Trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g., Letairis (ambrisentan), Opsumit (macitentan), Tracleer (bosentan)]

OR

4.2 For continuation of prior therapy

AND

5 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]

AND

6 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Cardiologist

AND

7 - Patient is unable to take oral medications [13]

Product Name: Upravi tablet/injection	
Diagnosis	Pulmonary Arterial Hypertension
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient demonstrates positive clinical response to therapy	
AND	
2 - Not taken in combination with a prostanoid/prostacyclin analogue [e.g., Flolan (epoprostenol), Ventavis (iloprost), Tyvaso/Remodulin/Orenitram (treprostinil)]	

3 . Endnotes

- A. Require right heart catheterization in order to confirm pulmonary arterial hypertension diagnosis: Per clinical consult with cardiologist, PAH specialist, and P&T committee recommendation, February 20, 2014.

4 . References

1. Flolan Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. August 2021.
2. Revatio Prescribing Information. Pfizer Inc. New York, NY. January 2023.
3. Ventavis Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. March 2022.
4. Tyvaso Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2022.
5. Remodulin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. July 2021.
6. Adcirca Prescribing Information. Eli Lilly and Company. Indianapolis, IN. September 2020.
7. Letairis Prescribing Information. Gilead Sciences, Inc. Foster City, CA. August 2019.
8. Tracleer Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
9. Veletri Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
10. Opsumit Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
11. Adempas Prescribing Information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ. September 2021.
12. Orenitram Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. May 2021.
13. Upravi Prescribing Information. Actelion Pharmaceuticals US, Inc. Titusville, NJ. July 2022.
14. Alyq Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. September 2021.
15. Tyvaso DPI Prescribing Information. United Therapeutics Corporation. Research Triangle Park, NC. May 2022.
16. Tadliq Prescribing Information. CMP Pharma, Inc. Farmville, NC. June 2022.
17. Liqrev Prescribing Information. CMP Pharma, Inc. Farmville, NC. April 2023.

Pulmozyme (dornase alfa inhalation solution)

Prior Authorization Guideline

Guideline Name	Pulmozyme (dornase alfa inhalation solution)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Pulmozyme*	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of cystic fibrosis (CF)	
Notes	*Prior Authorization may not apply depending on the plan

Product Name: Pulmozyme*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cystic fibrosis (CF)</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to Pulmozyme therapy</p>	
Notes	*Prior Authorization may not apply depending on the plan

2 . References

1. Pulmozyme Prescribing Information. Genentech, Inc, January 2018.
2. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013;187(7):680-9.
3. Flume PA, O'Sullivan BP, Robinson KA et al. Cystic fibrosis pulmonary guidelines. Am J Respir Crit Care Med. 2007;176:957-969

Pyrukynd (mitapivat)

Prior Authorization Guideline

Guideline Name	Pyrukynd (mitapivat)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Pyrukynd (mitapivat)
Hemolytic Anemia Indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2 . Criteria

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count) [A, 2, 3, 4]

AND

2 - Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: [B, 1, 2, 4, 5]

- Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant
- Patient is not homozygous for the c.1436G>A (p.R479H) variant
- Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

AND

3 - Hemoglobin is less than or equal to 10g/dL [1]

AND

4 - Patient has symptomatic anemia or is transfusion dependent [7]

AND

5 - Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs) [C, 2, 5]

AND

6 - Prescribed by or in consultation with a hematologist

Product Name: Pyrukynd	
Diagnosis	Hemolytic Anemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy [e.g., hemoglobin increase greater than or equal to 1.5g/dL from baseline, reduction in transfusions of greater than or equal to 33% in the number of red blood cell units transfused during the fixed dose period compared with the patient's historical transfusion burden, improvement in markers of hemolysis from baseline (e.g., bilirubin, lactated dehydrogenase [LDH], haptoglobin, reticulocyte count)]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a hematologist</p>	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a 1-month authorization should be issued one time for Pyrukynd gradual therapy discontinuation.

3 . Endnotes

- A. The first step in the evaluation of a person with possible PK deficiency is to establish if hemolysis is present. Hemolytic anemia is characterized by an increased reticulocyte count, increased indirect bilirubin, and possibly by increased LDH and decreased haptoglobin [4]
- B. In case of decreased PK activity, sequencing of PKLR gene is highly recommended to confirm the diagnosis [2]
- C. Since the hematological features of PK deficiency are not specific, the possibility of PK deficiency and other metabolic abnormalities should be considered in all patients displaying chronic hemolysis where an immune-mediated hemolytic process, red cell membrane defect, unstable hemoglobin, or paroxysmal nocturnal hemoglobinuria has been excluded [2]

4 . References

1. Pyrukynd (mitapivat) [prescribing information]. Agios Pharmaceuticals, Inc. Cambridge, MA. 02139
2. Bianchi, P., Fermo, E. et al. Addressing the diagnostic gaps in pyruvate kinase deficiency: Consensus recommendations on the diagnosis of pyruvate kinase deficiency. Available at <https://doi.org/10.1002/ajh.25325>. October 25, 2018. Accessed March 28, 2022.

3. National Organization for Rare Disorders and Foundation for Rare Blood Diseases. Voice of the Patient Report Pyruvate Kinase Deficiency. Available at https://rarediseases.org/wp-content/uploads/2020/01/NRD-2029-Voice-of-the-Patient-Report-PKD_FNL-1.pdf. Accessed March 28, 2022.
4. UpToDate Pyruvate Kinase Deficiency. Available at <https://www.uptodate.com/contents/pyruvate-kinase-deficiency>. Accessed March 28, 2022.
5. Samkari-AI, H., Van Beers, E. et al. The variable manifestations of disease in pyruvate kinase deficiency and their management. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7556504/>. Accessed March 28, 2022.
6. Clinical consult April 8, 2022.
7. May P & T Committe feedback. May 19, 2022.

Qinlock (riporetinib)

Prior Authorization Guideline

Guideline Name	Qinlock (riporetinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Qinlock (riporetinib)
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.

2 . Criteria

Product Name: Qinlock	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of gastrointestinal stromal tumor (GIST)	

AND

2 - Disease is advanced

AND

3 - Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib

Product Name: Qinlock

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Qinlock Prescribing Information. Deciphera Pharmaceuticals, LLC. Waltham, MA. December 2022.

Prior Authorization Guideline

Guideline Name	Quantity Limit General
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Guideline Note:

Effective Date:	3/15/2023
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Note:

For all other drugs subject to quantity limits, OptumRx may authorize coverage for additional quantities of medications listed on the Standard QL list for patients who meet the following criteria.

1 . Criteria

Product Name: Less than or equal to the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 Months (except for titration of loading-dose purposes)
Guideline Type	Administrative
Approval Criteria 1 - One of the following: 1.1 Quantity limit override requests must involve an FDA-approved indication	

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, patient requires a larger quantity to cover a larger surface area

Notes	Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline. **Commercially available strength/dose requires a formulary drug.
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Product Name: Greater than the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

OR

3.3 Higher dose or quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed higher than maximum doses for the diagnosis provided as generally safe and effective

Notes

*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day.

Reblozyl (luspatercept-aamt)

Prior Authorization Guideline

Guideline Name	Reblozyl (luspatercept-aamt)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Reblozyl (luspatercept-aamt)
Beta Thalassemia Indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions.
Myelodysplastic Syndromes with Ring Sideroblasts or Myelodysplastic/Myeloproliferative Neoplasm with Ring Sideroblasts and Thrombocytosis Associated Anemia Indicated for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of beta thalassemia major [3]</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient requires regular red blood cell (RBC) transfusions</p> <p style="text-align: center;">OR</p> <p>1.2 Diagnosis of transfusion-dependent beta thalassemia [3]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist • Oncologist 	

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation of a positive clinical response to therapy (e.g., reduction in RBC transfusion burden) [1,2]

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <p>1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)</p> <p style="text-align: center;">OR</p> <p>1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]</p> <p style="text-align: center;">AND</p> <p>3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p>	

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm (MDS-RS, MDS/MPN-RS-T)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]</p>	

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. April 2020.
2. Piga A, Perrotta S, Gamberini M, et al. Luspatercept improves hemoglobin levels and blood transfusion requirements in a study of patients with β -thalassemia. Blood 2019; 133 (12): 1279–1289.
3. Per clinical consult with oncologist, December 19, 2019.
4. Fenaux P, Platzbecker U, Ghulam J, et al. Luspatercept in patients with lower-risk myelodysplastic syndromes. N Engl J Med 2020; 382:140-151.

Prior Authorization Guideline

Guideline Name	Recorlev (levoketoconazole) - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Recorlev (levoketoconazole)
Cushing's Syndrome Indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative. Limitations of Use: RECORLEV is not approved for the treatment of fungal infections.

2 . Criteria

Product Name: Recorlev	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Cushing's syndrome demonstrated by urinary free cortisol (UFC) increase of 50% from baseline [3]

AND

2 - Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma)[1,2]

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Surgery has not been curative

AND

4 - Trial and failure for a minimum of 90 days, or intolerance to oral ketoconazole [A]

AND

5 - Prescribed by or in consultation with an endocrinologist

Product Name: Recorlev

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy as demonstrated by ONE of the following:

- Normalization of urinary free cortisol (UFC) [1]
- At least a 50% decrease in UFC levels [3]

Product Name: Recorlev

Approval Length | 6 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming diagnosis of Cushing's syndrome demonstrated by urinary free cortisol (UFC) increase of 50% from baseline [3]

AND

2 - Patient is being treated for endogenous hypercortisolemia (e.g., pituitary adenoma, ectopic tumor, adrenal adenoma)[1,2]

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Surgery has not been curative

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure for a minimum of 90 days, or intolerance to oral ketoconazole [A]

AND

5 - Prescribed by or in consultation with an endocrinologist

3 . Endnotes

- A. Per feedback from consultant, determining efficacy of ketoconazole therapy is difficult to determine as multiple dose adjustments often need to be made depending on patient's response. Consultant recommends failure to respond to therapy be defined as requiring more than 3-4 dose adjustments or no response after 4 months. [3]

4 . References

1. Recorlev [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc.; December 2021.
2. Guaraldi F, Salvatori R. Cushing Syndrome: Maybe Not So Uncommon of an Endocrine Disease. *The Journal of the American Board of Family Medicine*. 2012;25(2):199-208.
3. Per clinical consult with endocrinologist, February 11, 2022.

Regranex (becaplermin)

Prior Authorization Guideline

Guideline Name	Regranex (becaplermin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Regranex	
Approval Length	5 Months [1,2,A]
Guideline Type	Prior Authorization
Approval Criteria 1 - Patient has a lower extremity diabetic neuropathic ulcer [1] AND 2 - Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief) [1]	

2 . Endnotes

- A. Fifty percent of patients will achieve complete healing within 20 weeks with Regranex. Reassessment is required for further therapy. [1] According to the prescribing label, if the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks, continued treatment with Regranex should be reassessed. Postmarketing studies have demonstrated an increased risk of mortality secondary to malignancy observed in patients treated with greater than or equal to 3 tubes of Regranex gel. [1]

3 . References

1. Regranex Prescribing Information. Smith & Nephew, Inc. Forth Worth ,TX, March 2017.
2. Weiman TJ, Smiell JM, Su Y. Efficacy and safety of a topical gel formulation of recombinant human platelet-derived growth factor-BB (becaplermin) in patients with chronic neuropathic diabetic ulcers. *Diabetes Care* 1998;21:822-7.

Relyvrio (sodium phenylbutyrate and taurursodiol)

Prior Authorization Guideline

Guideline Name	Relyvrio (sodium phenylbutyrate and taurursodiol)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Relyvrio (sodium phenylbutyrate and taurursodiol)
Amyotrophic lateral sclerosis Indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

2 . Criteria

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis amyotrophic lateral sclerosis (ALS)	

AND

2 - Diagnosis of ALS is further supported by neurogenic changes in electromyography (EMG)
[2]

AND

3 - Patient has had ALS symptoms for less than or equal to 18 months

AND

4 - Patient has a percent (%) forced vital capacity (%FVC) or slow vital capacity (%SVC) greater than or equal to 60% at the start of treatment

AND

5 - Patient does not require permanent noninvasive ventilation or invasive ventilation

AND

6 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

Product Name: Relyvrio	
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of slowed disease progression from baseline	

AND

2 - Prescribed by or in consultation with a neurologist with expertise in the diagnosis of ALS

3 . Endnotes

- A. Great care should be taken to rule out diseases that can masquerade as ALS. An evolution of atypical symptoms and a lack of progression of typical symptoms are the most important "red flags" suggesting an alternative diagnosis. [2]

4 . References

1. Paganoni S, Macklin EA, Hendrix S, et al. Trial of Sodium Phenylbutyrate–Taurursodiol for Amyotrophic Lateral Sclerosis. *New England Journal of Medicine*. 2020;383(10):919-930.
2. Andersen PM, Abrahams S, Borasio GD, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) - revised report of an EFNS task force. *European Journal of Neurology*.
3. Paganoni S, Hendrix S, Dickson SP, et al. Long-term survival of participants in the CENTAUR trial of sodium phenylbutyrate-taurursodiol in amyotrophic lateral sclerosis. *Muscle & Nerve*. 2021;63(1):31-39.
4. ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/study/NCT03127514>. Accessed May 26, 2022.
5. Galvez-Jimenez N, Goyal NA. Disease-modifying treatment of amyotrophic lateral sclerosis. UpToDate Web site. <http://www.uptodate.com>. Accessed May 26, 2022.
6. Elman LB, McCluskey, L. Diagnosis of amyotrophic lateral sclerosis and other forms of motor neuron disease. UpToDate Web site. <http://www.uptodate.com>. Accessed May 26, 2022.
7. Relyvrio Prescribing Information. Amylyx Pharmaceuticals, Inc. Cambridge, MA. September 2022.

Prior Authorization Guideline

Guideline Name	Repository Corticotropin Gel Products - PA, NF
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
<p>Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.</p> <p>Exacerbations of Multiple Sclerosis [4, 5] Indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.</p> <p>All Other Disease States [A] *Please Note: The request for Acthar for the treatment of a condition other than Infantile Spasms (IS) or Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.</p> <p>[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tie the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.</p> <p>[Non-Approvable Use] Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).</p>

[Non-Approvable Use] Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome.

[Non-Approvable Use] Allergic States* [A] Serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Symptomatic sarcoidosis

[Non-Approvable Use] Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Drug Name: Purified Cortrophin Gel (repository corticotropin injection)

Exacerbations of Multiple Sclerosis [4, 5] Indicated for acute exacerbations of multiple sclerosis.

All Other Disease States [A] *Please Note: The request for Purified Cortrophin Gel for the treatment of a condition other than Exacerbations of Multiple Sclerosis (MS) is not authorized. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions.

[Non-Approvable Use] Rheumatic Disorders* [6, 7, A] Indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy); Ankylosing spondylitis; Acute gouty arthritis.

[Non-Approvable Use] Collagen Diseases* [8-10, A] Indicated during an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

[Non-Approvable Use] Dermatologic Diseases* [A] Indicated for severe erythema multiforme (Stevens-Johnson syndrome), severe psoriasis.

[Non-Approvable Use] Allergic States* [A] Indicated for atopic dermatitis, serum sickness.

[Non-Approvable Use] Ophthalmic Diseases* [14, A] Indicated for severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: allergic conjunctivitis, keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation.

[Non-Approvable Use] Respiratory Diseases* [11, A] Indicated for symptomatic sarcoidosis.

[Non-Approvable Use] Edematous States* [12, 13, 15, A] Indicated to induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Off Label Uses: Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

2 . Criteria

Product Name: Acthar Gel, Purified Cortrophin Gel [off-label]	
Diagnosis	Infantile Spasms (West Syndrome)
Approval Length	4 Week(s)
Guideline Type	Prior Authorization, Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of infantile spasms (West Syndrome)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a neurologist</p> <p style="text-align: center;">AND</p> <p>3 - Patient is less than 2 years of age</p>	

Product Name: Acthar Gel, Purified Cortrophin Gel	
Diagnosis	Multiple Sclerosis
Approval Length	3 Week(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of acute exacerbation of multiple sclerosis

AND

2 - Prescribed by or in consultation with a neurologist

AND

3 - One of the following:

3.1 Both of the following:

- Patient is new to therapy with corticotropin
- Trial and failure, contraindication, or intolerance to treatment with two high dose corticosteroid treatments (e.g., prednisone, IV methylprednisolone)

OR

3.2 All of the following:

- Patient's multiple sclerosis exacerbations have been treated in the past with corticotropin
- Patient has benefitted from treatment with corticotropin for acute exacerbations of multiple sclerosis
- Medication is being used to treat a new exacerbation of multiple sclerosis

Product Name: Acthar Gel, Purified Cortrophin Gel

Diagnosis

All Other Indications [A]

Approval Length

N/A - Requests for non-approvable diagnoses should not be approved

Guideline Type

Prior Authorization, Non Formulary

Approval Criteria

1 - The request for Acthar Gel and Purified Cortrophin Gel for the treatment of a condition other than Exacerbations of Multiple Sclerosis (MS) or Infantile Spasms (IS) is not authorized

and will not be approved. There is no consensus in current peer-reviewed medical literature regarding the efficacy, safety, or long-term consequences of using repository corticotropin over conventional corticosteroids in these steroid-responsive conditions:

- Rheumatic Disorders* [6, 7, A] As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis, Acute gouty arthritis.
- Collagen Diseases* [8-10, A] During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).
- Dermatologic Diseases* [A] Severe erythema multiforme, Stevens-Johnson syndrome, Severe psoriasis.
- Allergic States* [A] Serum sickness, Atopic dermatitis.
- Ophthalmic Diseases* [14, A] Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation; Allergic conjunctivitis.
- Respiratory Diseases* [11, A] Symptomatic sarcoidosis.
- Edematous State* [12, 13, 15, A] To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.
- Any other disease state not mentioned [A]*

Notes	*Other disease states lack published clinical literature to support the use of Acthar or Purified Cortrophin Gel [A]
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3 . Endnotes

- A. Grandfathered indications, although briefly mentioned in the labeling, do not have clinical studies in the prescribing information or medical literature supporting their use of Acthar or Purified Cortrophin Gel.

4 . References

1. Acthar prescribing information. Mallinckrodt ARD LLC. Bedminster, NJ. October 2021.
2. Baram TZ, Mitchell WG, Tournay A, et al. High-dose corticotropin (ACTH) versus prednisone for infantile spasms: a prospective, randomized, blinded study. Pediatrics. 1996 Mar; 97(3):375-379.
3. Hrachovy RA, Frost JD, Glaze DG. High-dose, long-duration versus low-dose, short-duration corticotropin therapy for infantile spasms. J Pediatr. 1994 May; 124(5): 803-806.
4. Thompson, AJ. Relative efficacy of IV methylprednisolone vs ACTH in acute relapse of MS. Neurology. 1989 July;39(7):969.

5. Citterio A, La Mantia L, Ciucci G, et al. Corticosteroids or ACTH for acute exacerbations in multiple sclerosis. *Cochrane Database of Systematic Reviews* 2000, Issue 4.
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Prior Authorization Guideline

Guideline Name	Restasis (cyclosporine 0.05%) - PA, NF
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Restasis (cyclosporine 0.05%) ophthalmic emulsion
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 . Criteria

Product Name: Brand Restasis, Generic cyclosporine 0.05% ophthalmic emulsion (Tier 1*)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

2 - One of the following [1, B]:

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

Notes

NOTE: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 1 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 2 or Tier 3

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion (Tier 2 or Tier 3*)

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

2 - One of the following [1, B]:

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

AND

3 - All of the following:

3.1 At least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Documentation provided stating that brand Restasis has not been effective

AND

3.3 Justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

Notes

Note: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 2 or Tier 3 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 1.

Product Name: Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion (Tier 1*)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)</p> <p style="text-align: center;">AND</p> <p>2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])</p>	
Notes	NOTE: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 1 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 2 or Tier 3

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion (Tier 2 or Tier 3*)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)</p> <p style="text-align: center;">AND</p> <p>2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])</p>	

AND

3 - All of the following:

3.1 At least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Documentation provided stating that brand Restasis has not been effective

AND

3.3 Justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

Notes

Note: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 2 or Tier 3 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 1.

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

2 - One of the following [1, B]:

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

AND

3 - All of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Submission of documentation provided stating that brand Restasis has not been effective

AND

3.3 Submission of justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

3 . Endnotes

- A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in

addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

- B. The FDA-approved indication states that during clinical trials, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. [1]

4 . References

1. Restasis Prescribing Information. Allergan Inc. Irvine, CA. July 2017.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed May 28, 2021.

Prior Authorization Guideline

Guideline Name	Retevmo (selpercatinib)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Retevmo (selpercatinib)
<p>Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic RET fusion-positive non-small cell lung cancer, as detected by an FDA-approved test.</p> <p>Medullary Thyroid Cancer (MTC) Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC), as detected by an FDA-approved test, who require systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).</p> <p>Thyroid Cancer Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer, as detected by an FDA-approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).</p> <p>Solid Tumors Indicated for the treatment of adult patients with locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of</p>

response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none">• Locally Advanced• Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) - approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Retevmo

Diagnosis	Medullary Thyroid Cancer (MTC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of medullary thyroid cancer (MTC)

AND

2 - Disease is ONE of the following:

- Advanced
- Metastatic

AND

3 - Patient is 12 years of age or older

AND

4 - Disease has presence of rearranged during transfection (RET) gene mutation tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

5 - Disease requires treatment with systemic therapy

AND

6 - Prescribed by or in consultation with an oncologist

Product Name: Retevmo	
Diagnosis	Thyroid Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of thyroid cancer</p> <p style="text-align: center;">AND</p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> • Advanced • Metastatic <p style="text-align: center;">AND</p> <p>3 - Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>5 - Disease requires treatment with systemic therapy</p> <p style="text-align: center;">AND</p> <p>6 - ONE of the following</p>	

- Patient is radioactive iodine-refractory
- Radioactive iodine therapy is not appropriate

AND

7 - Prescribed by or in consultation with an endocrinologist or an oncologist

Product Name: Retevmo	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of solid tumors</p> <p style="text-align: center;">AND</p> <p>2 - Disease is ONE of the following:</p> <ul style="list-style-type: none"> • Locally Advanced • Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) [A, 1]</p> <p style="text-align: center;">AND</p> <p>4 - ONE of the following:</p> <ul style="list-style-type: none"> • Disease has progressed on or following prior systemic treatment (e.g., chemotherapy) 	

- There are no satisfactory alternative treatment options

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Retevmo	
Diagnosis	Non-Small Cell Lung Cancer, Medullary Thyroid Cancer (MTC), Thyroid Cancer, Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . Endnotes

- A. An FDA-approved companion diagnostic test for the detection of RET gene fusions and RET gene mutations in plasma or in tumors other than NSCLC and thyroid cancer is not currently available.

4 . References

1. Retevmo Prescribing Information. Lilly USA. Indianapolis, IN. September 2022.

Revcovi (elapegademase-IvIr)

Prior Authorization Guideline

Guideline Name	Revcovi (elapegademase-IvIr)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Renvovi (elapegademase-IvIr)
Adenosine deaminase severe combined immune deficiency (ADA-SCID) Indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

2 . Criteria

Product Name: Renvovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID)

Product Name: Revcovi

Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . References

1. Revcovi Prescribing Information. Leadiant Biosciences, Inc. Gaithersburg, MD. December 2020.
2. Immune Deficiency Foundation Patient & Family Handbook for Primary Immunodeficiency Diseases. Fifth Edition. 2013.

Prior Authorization Guideline

Guideline Name	Revlimid (lenalidomide)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Revlimid (lenalidomide)
<p>Myelodysplastic Syndromes Indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]</p> <p>Multiple Myeloma Revlimid in combination with dexamethasone is indicated for the treatment of adult patients with multiple myeloma (MM). Also Revlimid is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]</p> <p>Mantle Cell Lymphoma (MCL) Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]</p> <p>Follicular Lymphoma (FL) Revlimid in combination with a rituximab product, is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]</p> <p>Marginal Zone Lymphoma (MZL) Revlimid in combination with a rituximab product, is</p>

indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL). Limitations of Use: Not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials. [A]

2 . Criteria

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Myelodysplastic Syndromes (MDS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of symptomatic or transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality [2]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist/hematologist</p>	

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Multiple Myeloma (MM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of multiple myeloma</p>	

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Mantle Cell Lymphoma (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of relapsed or progressed mantle cell lymphoma (MCL)	
AND	
2 - Prescribed by or in consultation with an oncologist/hematologist	

Product Name: Brand Revlimid, Generic lenalidomide	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of follicular lymphoma (FL) that has been previously treated	
AND	

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide

Diagnosis	Marginal Zone Lymphoma (MZL)
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of marginal zone lymphoma (MZL) that has been previously treated

AND

2 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Brand Revlimid, Generic lenalidomide

Diagnosis	All Indications Listed Above
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. Although the prescribing information for Revlimid states that it is not indicated and is not recommended for the treatment of patients with CLL outside of controlled clinical trials due to the increased risk of mortality, current NCCN practice guideline still recommends

single agent lenalidomide or in combination with rituximab for relapsed/refractory CLL.
[1, 2]

4 . References

1. Revlimid Prescribing Information. Celgene Corporation. Princeton, NJ. December 2022.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at: www.nccn.org. Accessed March 8, 2023.

Prior Authorization Guideline

Guideline Name	Reyvow (lasmiditan) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Reyvow (lasmiditan)
Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Reyvow is not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Reyvow	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of migraine with or without aura	

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient has less than 15 headache days per month [2]

AND

4 - Patient is 18 years of age or older [A]

AND

5 - One of the following: [3]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 3]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

AND

8 - Will not be used concomitantly with central nervous system (CNS) depressants (e.g., alprazolam, phenobarbital, alcohol)

AND

9 - Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 8 hours after taking each dose of Reyvow

AND

10 - Trial and failure, contraindication, or intolerance to both of the following:

- Nurtec
- Ubrelvy

Product Name: Reyvow	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p>AND</p>	

2 - Will not be used for preventive treatment of migraine

AND

3 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Reyvow

Approval Length	3 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura

AND

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Submission of medical records (e.g., chart notes) confirming patient has less than 15 headache days per month [2]

AND

4 - Patient is 18 years of age or older [A]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [3]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [B, 3]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication

AND

7 - Prescribed by or in consultation with one of the following specialists:

- Neurologist
- Pain specialist
- Headache specialist [C]

AND

8 - Will not be used concomitantly with central nervous system (CNS) depressants (e.g., alprazolam, phenobarbital, alcohol)

AND

9 - Submission of medical records (e.g., chart notes) confirming that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 8 hours after taking each dose of Reyvow

AND

10 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

- Nurtec
- Ubrelvy

3 . Endnotes

- A. The safety and effectiveness in pediatric patients has not been established [1].
- B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [4].
- C. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS) [5]

4 . References

1. Reyvow Prescribing Information. Lilly USA, LLC. Indianapolis , IN. September 2022.
2. Goadsby PJ, Wietecha LA, Dennehy EB, et al. Phase 3 randomized, placebo-controlled, double-blind study of lasmiditan for acute treatment of migraine. *Brain*. 2019 Jul 1;142(7):1894-1904.
3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. *Headache*. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10;86(19):1818-26.
5. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed February 2, 2023.

Prior Authorization Guideline

Guideline Name	Rezlidhia (olutasidenib) - PA, NF
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Rezlidhia (olutasidenib)
Acute Myeloid Leukemia (AML) Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name: Rezlidhia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acute myeloid leukemia (AML)	

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Rezlidhia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

2.2 For continuation of prior therapy

Product Name: Rezlidhia

Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay)

or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Tibsovo (ivosidenib)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with an oncologist/hematologist

3 . References

1. Rezlidhia Prescribing Information. Rigel Pharmaceuticals, Inc. South San Francisco, CA. December 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on January 3, 2023.

Prior Authorization Guideline

Guideline Name	Rezurock (belumosudil) - PA, NF
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Rezurock (belumosudil)
Chronic graft-versus-host disease Indicated for the treatment of chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients 12 years and older.

2 . Criteria

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic graft-versus-host disease

AND

2 - Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

AND

3 - Patient is 12 years of age or older

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist
- Physician experienced in the management of transplant patients

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Rezurock	
Diagnosis	Chronic graft-versus-host disease
Approval Length	12 month(s)

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic graft-versus-host disease</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist • Oncologist • Physician experienced in the management of transplant patients 	

Product Name: Rezero	
Diagnosis	Chronic graft-versus-host disease - Twice daily (BID) Therapy
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Patient is using medication concomitantly with one of the following:</p> <ul style="list-style-type: none"> • Strong CYP3A inducer (e.g., carbamazepine, phenobarbital, phenytoin, rifampin) 	

- Proton pump inhibitor (e.g., omeprazole, pantoprazole, lansoprazole)

3 . References

1. Rezero Prescribing Information. Kadmon Pharmaceuticals, LLC. Warrendale, PA. July 2021.

Prior Authorization Guideline

Guideline Name	Riluzole Products - PA, NF
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Exservan (riluzole film), Rilutek (riluzole tablets), Tiglutik (riluzole suspension)
Amyotrophic Lateral Sclerosis (ALS) Indicated for the treatment of patients with amyotrophic lateral sclerosis (ALS).

2 . Criteria

Product Name: Brand Rilutek, Tiglutik	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of amyotrophic lateral sclerosis (ALS)	

AND

2 - Trial and failure or intolerance to generic riluzole tablets

Product Name: Exservan

Approval Length | 12 month(s)

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Trial and failure or intolerance to generic riluzole tablets and Tiglutik suspension

Product Name: Generic riluzole

Approval Length | 12 month(s)

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

Product Name: Exservan

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of amyotrophic lateral sclerosis (ALS)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure or intolerance to both of the following:

- generic riluzole tablets
- Tiglutik suspension

3 . References

1. Rilutek Prescribing Information. Covis Pharma. Zug, Switzerland. March 2020.
2. Tiglutik Prescribing Information. ITF Pharma, Inc. Berwyn, PA. April 2021.
3. Exservan Prescribing Information. Aquestive Therapeutics. Warren, NJ. April 2020.

Prior Authorization Guideline

Guideline Name	Rinvoq (upadacitinib)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Rinvoq (upadacitinib)
<p>Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.</p> <p>Psoriatic Arthritis (PsA) Indicated for the treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.</p> <p>Ankylosing Spondylitis (AS) Indicated for the treatment of adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended.</p> <p>Non-radiographic Axial Spondyloarthritis (nr-AxSpA) Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine.</p>

Atopic Dermatitis (AD) Indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Rinvoq is not recommended for use in combination with other JAK inhibitors, biological therapies for ulcerative colitis, or with potent immunosuppressants such as azathioprine and cyclosporine.

2 . Criteria

Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active rheumatoid arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:</p> <ul style="list-style-type: none"> • methotrexate 	

- leflunomide
- sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline <p>AND</p> <p>2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*</p>	

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [4]:</p> <ul style="list-style-type: none"> • Actively inflamed joints • Dactylitis • Enthesitis • Axial disease • Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Rheumatologist <p style="text-align: center;">AND</p> <p>4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)</p>	

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active ankylosing spondylitis</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]</p> <p style="text-align: center;">AND</p> <p>4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia, Enbrel, Humira, Amjevita, Simponi)</p> <p style="text-align: center;">AND</p> <p>5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*</p>	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes

*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq

Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active non-radiographic axial spondyloarthritis

AND

2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 5]

AND

3 - Prescribed by or in consultation with a rheumatologist

AND

4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Cimzia)

AND

6 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-AxSpA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following [1, 5]:	
<ul style="list-style-type: none">Disease activity (e.g., pain, fatigue, inflammation, stiffness)	

- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine or cyclosporine)*

Notes

*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe atopic dermatitis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <ul style="list-style-type: none"> • Involvement of at least 10% body surface area (BSA) • SCORing Atopic Dermatitis (SCORAD) index value of at least 25 [A] <p style="text-align: center;">AND</p>	

4 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Allergist/Immunologist

AND

5 - Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication, or intolerance to at least ONE of the following:

- Medium or higher potency topical corticosteroid
- Pimecrolimus cream
- Tacrolimus ointment
- Eucrisa (crisaborole) ointment

AND

6 - One of the following:

6.1 Trial and failure of a minimum 12-week supply of at least one systemic drug product for the treatment of atopic dermatitis (examples include, but are not limited to, Adbry [tralokinumab-ldrm], Dupixent [dupilumab], etc.)

OR

6.2 Patient has a contraindication, intolerance, or treatment is inadvisable with both of the following FDA-approved atopic dermatitis therapies:

- Adbry (tralokinumab-ldrm)
- Dupixent (dupilumab)

AND

7 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy as evidenced by at least ONE of the following:</p> <ul style="list-style-type: none"> • Reduction in body surface area involvement from baseline • Reduction in SCORing Atopic Dermatitis (SCORAD) index value from baseline [A] <p style="text-align: center;">AND</p> <p>2 - Not used in combination with other JAK inhibitors, biologic immunomodulators (e.g., Dupixent, Adbry), or other immunosuppressants (e.g., azathioprine, cyclosporine)*</p>	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p>	

2 - One of the following [6, 7]:

- Greater than 6 stools per day
- Frequent blood in the stools
- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [6, 7]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., Humira, Amjevita, Simponi)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 6, 7]:</p> <ul style="list-style-type: none"> Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline Reversal of high fecal output state <p style="text-align: center;">AND</p> <p>2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or with potent immunosuppressants (e.g., azathioprine, cyclosporine)*</p>	
Notes	*Rinvoq may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Background

Clinical Practice Guidelines			
Table 1. Relative potencies of topical corticosteroids [8]			
Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05

	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
	Alclometasone dipropionate	Cream, ointment	0.05

Low potency	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

- A. The Scoring Atopic Dermatitis (SCORAD) index is a clinical tool for assessing the severity of atopic dermatitis lesions based on affected body area and intensity of plaque characteristics. [9, 10] The extent and severity of AD over the body area (A) and the severity of 6 specific symptoms (erythema, edema/papulation, excoriations, lichenification, oozing/crusts, and dryness) (B) are assessed and scored by the Investigator. Subjective assessment of itch and sleeplessness is scored by the patient (C). The SCORAD score is a combined score ($A/5 + 7B/2 + C$) with a maximum of 103. Higher scores indicate greater severity/worsened state. A score of 25 to 50 indicates moderate disease severity and greater than 50 indicates severe disease. [11]

5 . References

1. Rinvoq Prescribing Information. AbbVie Biotechnology Ltd. North Chicago, IL. October 2022.
2. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
3. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.
6. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413.
7. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol.* 2020;158:1450-1461.

8. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol*. 2014; 71(1):116-32.
9. European Task Force on Atopic Dermatitis. Severity scoring of atopic dermatitis: the SCORAD index. Consensus report of the European Task Force on atopic dermatitis. *Dermatology*. 1993; 186:23-31.
10. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. *Lancet* 2017; 389(10086)(suppl):2287-2303.
11. Oranje AP. Practical issues on interpretation of scoring atopic dermatitis: SCORAD index, objective SCORAD, patient-oriented SCORAD and three-item severity score. *Curr Probl Dermatol*. 2011; 41:149-55.

Prior Authorization Guideline

Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
<p>Follicular Lymphoma Indicated for the treatment of adult patients with: 1) Relapsed or refractory, follicular lymphoma as a single agent 2) Previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy 3) Non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.</p> <p>Diffuse Large B-cell Lymphoma Indicated for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens. Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.</p> <p>Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of adult patients with previously untreated and previously treated CLL in combination with fludarabine and cyclophosphamide (FC). Limitations of Use: Initiate treatment with Rituxan Hycela only after patients have received at least one full dose of a rituximab product by intravenous infusion. Rituxan Hycela is not indicated for the treatment of non-malignant conditions.</p>

2 . Criteria

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of follicular lymphoma</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Disease is relapsed or refractory</p> <p style="text-align: center;">OR</p> <p> 2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy</p> <p style="text-align: center;">OR</p> <p> 2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy</p> <p style="text-align: center;">OR</p> <p> 2.4 Both of the following</p>	

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)	
Diagnosis	Diffuse Large B-cell Lymphoma
Approval Length	12 months [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of diffuse large B-cell lymphoma</p> <p>AND</p> <p>2 - Disease is previously untreated</p> <p>AND</p> <p>3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy</p> <p>AND</p> <p>4 - One of the following:</p>	

4.1 Trial and failure, or intolerance to Ruxience

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

5 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rituxan Hycela (rituximab and hyaluronidase human)

Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 months [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia

AND

2 - Medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

3 . Endnotes

- A. Treatment for DLBCL consists of up to 8 cycles of 21 days each, a total duration of 6 months [1,3]. There is little evidence that use of rituximab as continuation therapy following R-CHOP induction provides additional benefit above induction alone. [2] This is in contrast with follicular lymphoma, where evidence does support maintenance [4] therapy and NCCN recommends consolidation with rituximab monotherapy [3]. However, to account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
- B. Treatment for CLL consists of up to 6 cycles of 28 days each, a total duration of 6 months [1]. To account for potential delays in therapy without interrupting treatment, a 12 month authorization is provided.
- C. An FDA-approved biosimilar is an appropriate substitute for rituximab. [3]
- D. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [4]

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Prior Authorization Guideline

Guideline Name	Rituximab
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Rituxan (rituximab)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older.

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. Limitation of Use: Rituxan is not recommended for use in patients with severe, active infections.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination fludarabine

and cyclophosphamide (FC). Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adult patients with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult and pediatric patients 2 years of age and older in combination with glucocorticoids. Limitations of Use: Rituxan is not recommended for use in patients with severe, active infections.

Pemphigus Vulgaris Indicated for the treatment of moderate to severe Pemphigus Vulgaris (PV) in adult patients.

Off Label Uses: Immune Thrombocytopenic Purpura (ITP) Has been used for the treatment of immune or idiopathic thrombocytopenic purpura. [1, 2] Overall response rates of 35% to 52% in patients with refractory idiopathic thrombocytopenic purpura. [3, 4]

Waldenstrom's Macroglobulinemia Has been used for the treatment of relapsed/refractory Waldenstrom's macroglobulinemia. Rituximab monotherapy (1 to 8 cycles) has shown efficacy in limited studies. [5-8]

Drug Name: Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Rheumatoid Arthritis (RA) In combination with methotrexate, is indicated for the treatment of adult patients with moderately- to severely-active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Off Label Uses: Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt

lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

Drug Name: Riabni (rituximab-arrx)

Non-Hodgkin's Lymphoma (NHL) Indicated for the treatment of patients with: a. Relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent. b. Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy. c. Non-progressing (including stable disease) low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma, as a single agent, after first-line CVP chemotherapy. d. Previously untreated diffuse large B-cell, CD20-positive non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens.

Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC).

Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) Indicated for the treatment of adults with Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in combination with glucocorticoids.

Rheumatoid Arthritis (RA) Indicated in combination with methotrexate for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies.

Off Label Uses: Pediatric Non-Hodgkin's Lymphoma (NHL) Indicated for previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL) or mature B-cell acute leukemia (B-AL) in combination with chemotherapy in pediatric patients aged 6 months and older. [25, C, D]

2 . Criteria

Product Name: Rituxan, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

AND

4.1.2 Trial and failure, contraindication, or intolerance to BOTH of the following:

- Actemra (tocilizumab)

- Orencia (abatacept)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Trial and failure or intolerance to both of the following:

- Ruxience
- Truxima

AND

6 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Ruxience, Truxima	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately- to severely-active rheumatoid arthritis</p> <p style="text-align: center;">AND</p> <p>2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [26, 27]:</p>	

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate [A]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*

- Cimzia (certolizumab)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or Xeljanz XR (tofacitinib ER)

OR

4.2 Continuation of prior rituximab therapy, defined as no more than a 45-day gap in therapy

AND

5 - Prescribed by or in consultation with a rheumatologist

Notes	*Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Rituxan, Ruxience, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [10, 26, 27]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline <p style="text-align: center;">AND</p> <p>2 - At least 16 weeks have elapsed since last course of therapy [B]</p>	

Product Name: Ruxience, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following: [10]</p> <ul style="list-style-type: none"> • Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma • Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <ul style="list-style-type: none"> • Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma 	

- Used as first-line treatment in combination with chemotherapy

OR

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label) [25, C, D]

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)

- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

Product Name: Riabni, Rituxan	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following: [10]</p> <ul style="list-style-type: none"> • Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma • Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens <p>OR</p> <p>1.2 Both of the following:</p> <ul style="list-style-type: none"> • Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma • Used as first-line treatment in combination with chemotherapy <p>OR</p>	

1.3 All of the following:

- Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma
- Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy
- Followed by rituximab used as monotherapy for maintenance therapy

OR

1.4 Both of the following: [1]

1.4.1 Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma

AND

1.4.2 One of the following:

- Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy
- Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy

OR

1.5 Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

OR

1.6 All of the following (off-label for Riabni) [25, C, D]:

1.6.1 Diagnosis of one of the following previously untreated, advanced stage indications:

- CD-20-positive diffuse large B-cell lymphoma (DLBCL)
- Burkitt lymphoma (BL)
- Burkitt-like lymphoma (BLL)
- Mature B-cell acute leukemia (B-AL)

AND

1.6.2 Patient is 6 months of age or older

AND

1.6.3 Used in combination with chemotherapy

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to both of the following:

- Ruxience
- Truxima

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Ruxience, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]	
AND	
2 - Used in combination with fludarabine and cyclophosphamide	

Product Name: Riabni, Rituxan	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with fludarabine and cyclophosphamide</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Trial and failure, or intolerance to both of the following:</p> <ul style="list-style-type: none"> • Ruxience • Truxima <p style="text-align: center;">OR</p> <p>3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen</p>	

Product Name: Rituxan	
Diagnosis	Immune or Idiopathic Thrombocytopenic Purpura [1, 2] (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of immune or idiopathic thrombocytopenic purpura (off-label) [3, 4, 11]

AND

2 - Trial and failure, contraindication, or intolerance to at least ONE of the following: [12]

- Glucocorticoids (e.g., prednisone, methylprednisolone)
- Immunoglobulins (e.g., IVIg)
- Splenectomy

AND

3 - Documented platelet count of less than $50 \times 10^9 / L$ [11]

Product Name: Rituxan

Diagnosis	Pemphigus Vulgaris
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of moderate to severe Pemphigus Vulgaris

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Rituxan

Diagnosis	Pemphigus Vulgaris
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to Rituxan therapy</p>	

Product Name: Rituxan	
Diagnosis	Waldenstrom's macroglobulinemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of relapsed/refractory Waldenstrom's macroglobulinemia (off-label) [1, 2, 5-8]</p>	

Product Name: Ruxience, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none"> • Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) • Microscopic Polyangiitis <p style="text-align: center;">AND</p> <p>2 - Used in combination with glucocorticoids (e.g., prednisone)</p> <p style="text-align: center;">AND</p>	

3 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Riabni, Rituxan	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none">• Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)• Microscopic Polyangiitis <p style="text-align: center;">AND</p> <p>2 - Used in combination with glucocorticoids (e.g., prednisone)</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Trial and failure, or intolerance to both of the following:</p> <ul style="list-style-type: none">• Ruxience• Truxima <p style="text-align: center;">OR</p> <p>3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen</p>	

AND

4 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist
- Rheumatologist

3 . Endnotes

- A. Aggressive, continuous and early treatment with DMARDs may slow the destructive processes in RA by preventing or delaying cartilage and bone destruction. [11] Often used in combination, the most commonly prescribed DMARDs include hydroxychloroquine, sulfasalazine, leflunomide and methotrexate, with methotrexate being the gold standard.
- B. An open-label extension analysis of RA patients previously treated with Rituxan was conducted. Patients were eligible for the second course if they demonstrated a greater than or equal to 20% reduction in both swollen joint count and the tender joint count at any visit 16 weeks after initial treatment or later and had active disease (swollen joint count greater than or equal to 8 and tender joint count greater than or equal to 8). Repeat courses of treatment were administered at the investigator's discretion, with a minimum interval between treatment courses of 16 weeks. [15]
- C. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [22]
- D. An FDA-approved biosimilar is an appropriate substitute for rituximab. [23, 25]

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Prior Authorization Guideline

Guideline Name	Romidepsin Products
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Guideline Note:

Effective Date:	3/1/2022
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1 . Indications

Drug Name: Istodax (romidepsin), Romidepsin (romidepsin)
Cutaneous T-cell lymphoma (CTCL) Indicated for the treatment of CTCL in adult patients who have received at least one prior systemic therapy.

2 . Criteria

Product Name: Istodax, Romidepsin	
Diagnosis	Cutaneous T-cell lymphoma (CTCL)
Approval Length	12 Month [2, A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL)

AND

2 - Trial and failure, contraindication, or intolerance to one systemic therapy for the treatment of CTCL [e.g., Trexall (methotrexate), Targretin (bexarotene), cyclophosphamide] [B]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Istodax, Romidepsin	
Diagnosis	Cutaneous T-cell lymphoma (CTCL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. A 12-month length of authorization is an appropriate amount of time for approval as the minimum is 6 cycles (6 months) and there is no established maximum number of cycles for CTCL. [2]
- B. Examples of CTCL systemic therapies include: Campath (alemtuzumab), cyclophosphamide, Doxil (liposomal doxorubicin), Extracorporeal photopheresis, Folutyn (pralatrexate), Gemzar (gemcitabine), Interferon-alpha , Leukeran (chlorambucil), Nipent (pentostatin), Targretin (bexarotene), Temodar (temozolamide), Toposar (etoposide), Trexall (methotrexate), Velcade (bortezomib). [3]

4 . References

1. Istodax prescribing information. Celgene Corporation. Summit, NJ. July 2021.
2. Per clinical consult with oncologist, September 7, 2011.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Primary Cutaneous Lymphomas. v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed March 5, 2021.
4. Romidepsin prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. March 2020.

Prior Authorization Guideline

Guideline Name	Roszet (rosuvastatin/ezetimibe) - PA, NF
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Roszet (rosuvastatin/ezetimibe)
Non-familial hyperlipidemia Indicated as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).
Homozygous familial hypercholesterolemia (HoFH) Indicated alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Roszet	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization, Non-Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Non-familial hyperlipidemia
- Homozygous familial hypercholesterolemia (HoFH)

AND

2 - Submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication, or intolerance to two of the following:

- rosuvastatin
- atorvastatin
- simvastatin

AND

3 - Submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, or intolerance to ezetimibe

AND

4 - Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination

Product Name: Roszet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization, Non-Formulary
Approval Criteria	
1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy	

3 . References

1. Roszet Prescribing Information. Althera Pharmaceuticals LLC. Morristown, NJ. May 2021.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018
AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-57.

Prior Authorization Guideline

Guideline Name	Rozlytrek (entrectinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Rozlytrek (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.
Solid Tumors Indicated for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy.

2 . Criteria

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - Patient has ROS1 rearrangement positive tumor(s)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Rozlytrek

Diagnosis	Solid Tumors
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.) [A]

AND

2 - Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions) [2]

AND

3 - Disease is one of the following:

- Metastatic
- Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

4 - One of the following:

- Disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) [3]
- Disease has no satisfactory alternative treatments

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Rozlytrek	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC), Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. The most common cancers listed in the pivotal trials which evaluated the efficacy of Rozlytrek were: sarcoma, lung, salivary gland tumors, breast, thyroid and colorectal cancer. [1]

4 . References

1. Rozlytrek Prescribing Information. Genentech USA, Inc. South San Francisco, CA. August 2019.
2. Drilon A, Nagasubramanian R, Blake JF, et al. A next-generation TRK kinase inhibitor overcomes acquired resistance to prior TRK kinase inhibition in patients with TRK fusion-positive solid tumors. *Cancer Discov.* 2017 Sep;7(9):963-972.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer. v.7.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed September 12, 2019.

Prior Authorization Guideline

Guideline Name	Rubraca (rucaparib) - PA, NF
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Rubraca (rucaparib)
<p>Maintenance Treatment of BRCA-mutated Recurrent Ovarian cancer Indicated for the maintenance treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.</p> <p>Metastatic Castration-Resistant Prostate Cancer with BRCA Mutations Indicated for the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)- associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.</p>

2 . Criteria

Product Name: Rubraca	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Epithelial ovarian cancer • Fallopian tube cancer • Primary peritoneal cancer <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Trial and failure, contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> • Lynparza • Zejula <p style="text-align: center;">OR</p> <p>2.2 For continuation of prior therapy</p>	

Product Name: Rubraca	
Diagnosis	Ovarian Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Epithelial ovarian cancer • Fallopian tube cancer • Primary peritoneal cancer 	

AND

2 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to one of the following:

- Lynparza
- Zejula

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy

Product Name: Rubraca

Diagnosis	Prostate Cancer
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of castration-resistant prostate cancer (CRPC)

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Lynparza

OR

2.2 For continuation of prior therapy

Product Name: Rubraca	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of castration-resistant prostate cancer (CRPC)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Lynparza</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy</p>	

Product Name: Rubraca	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Rubraca Prescribing Information. Clovis Oncology, Inc. Boulder, CO. December 2022.

2. U.S. Food and Drug Administration [website]: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm> Accessed July 9, 2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Ovarian Cancer - v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed June 15, 2022.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 9, 2021.

Rydapt (midostaurin)

Prior Authorization Guideline

Guideline Name	Rydapt (midostaurin)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Rydapt (midostaurin) capsules
Acute Myeloid Leukemia Indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Limitations of Use: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.
Aggressive Systemic Mastocytosis, Systemic Mastocytosis with Associated Hematological Neoplasm, or Mast Cell Leukemia Indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

2 . Criteria

Product Name: Rydapt	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 Month [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of newly diagnosed acute myeloid leukemia (AML)</p> <p style="text-align: center;">AND</p> <p>2 - FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [5]</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist • Oncologist 	

Product Name: Rydapt	
Diagnosis	Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), and Mast Cell Leukemia (MCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [4]

- Aggressive systemic mastocytosis (ASM)
- Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
- Mast cell leukemia (MCL)

AND

2 - Prescribed by or in consultation with one of the following:

- Hematologist
- Oncologist

Product Name: Rydapt	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Rydapt (midostaurin) therapy	

3 . Endnotes

- A. Although Rydapt (midostaurin) is not FDA-approved for maintenance therapy, the pivotal trial was designed to include induction, re-induction (if indicated), post-remission (consolidation), and maintenance therapy for a total of 12 months. Therapy significantly improved event free survival and overall survival. [1-3]

4 . References

1. Rydapt Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. June 2018.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed January 16, 2019.
3. Stone RM, Mandrekar S, Sanford BL, et al. The multi-kinase inhibitor midostaurin (M) prolongs survival compared with placebo (P) in combination with daunorubicin (D)/cytarabine (C) induction (ind), high-dose c consolidation (consol), and as maintenance (maint) therapy in newly diagnosed acute myeloid leukemia (AML) patients (pts) age 18-60 with FLT3 Mutations (mut): an international prospective randomized (rand) p-controlled double-blind trial (CALGB 10603/RATIFY [Alliance]). *Blood*. 2015 Dec;126:6.
4. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Systemic mastocytosis v.2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed January 16, 2019.
5. U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/cm301431.htm>. Accessed January 17, 2019.

Prior Authorization Guideline

Guideline Name	Sabril (vigabatrin), Vigadrone
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Sabril (vigabatrin), Vigadrone (vigabatrin)
Refractory Complex Partial Seizures Indicated as adjunctive therapy for adults and pediatric patients 2 years of age and older with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Sabril/Vigadrone is not indicated as a first line agent for complex partial seizures.
Infantile Spasms (1 Month to 2 Years of Age) Indicated as monotherapy for pediatric patients with infantile spasms (IS) 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

2 . Criteria

Product Name: Generic vigabatrin, Vigadrone	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following

1.1 Diagnosis of infantile spasms [A]

AND

1.2 Patient is 1 month to 2 years of age

OR

2 - All of the following:

2.1 Diagnosis of complex partial seizures

AND

2.2 Patient is 2 years of age or older

AND

2.3 Used as adjunctive therapy

AND

2.4 One of the following:

2.4.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

OR

2.4.2 For continuation of prior therapy

Product Name: Brand Sabril	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 All of the following:</p> <p>1.1.1 Diagnosis of infantile spasms [A]</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient is 1 month to 2 years of age</p> <p style="text-align: center;">AND</p> <p>1.1.3 One of the following:</p> <p>1.1.3.1 Trial and failure or intolerance to generic vigabatrin tablets or oral suspension</p> <p style="text-align: center;">OR</p> <p>1.1.3.2 For continuation of prior therapy if the patient is established on brand Sabril</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following: [A]</p> <p>1.2.1 Diagnosis of complex partial seizures</p>	

AND

1.2.4 Patient is 2 years of age or older

AND

1.2.2 Used as adjunctive therapy

AND

1.2.3 One of the following:

1.2.3.1 Both of the following:

1.2.3.1.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants [e.g., Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)] [B]

AND

1.2.3.1.2 Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

OR

1.2.3.2 For continuation of prior therapy if the patient is established on brand Sabril

Product Name: Generic vigabatrin, Vigadrone, Brand Sabril	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

- A. Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) program overview: Vigabatrin Sponsors have created Vigabatrin REMS program to administer the REMS process, which facilitates access to vigabatrin only through select specialty and inpatient pharmacies. The REMS includes the following elements: 1) Patient Guide: outlines the vision loss that can occur with vigabatrin treatment; 2) Elements to Assure Safe Use (ETASU): Vigabatrin Sponsors will maintain a database of certified prescribers (e.g., must counsel regarding the risks associated with vigabatrin, including vision loss; ensure periodic visual monitoring is performed on an ongoing basis, report any adverse event suggestive of vision loss; enrolling patients taking vigabatrin in the REMS program) and will ensure that prescribers comply with the requirements of the REMS and may de-certify noncompliant prescribers. [3] Assessing the effectiveness of vigabatrin should be done within 12 weeks for CPS patients and within 2-4 weeks for IS. Vision monitoring is mandatory in adults and it is required to the extent possible in infants at baseline (no later than 4 weeks after starting vigabatrin) and at least 3 months while on therapy. Vision testing is also required about 3-6 months after the discontinuation of vigabatrin therapy. [1, 2] Under REMS requirement, pharmacies that dispense vigabatrin will be specially certified. Vigabatrin Sponsors will ensure that each patient treated with vigabatrin is enrolled in the Vigabatrin REMS before vigabatrin is dispensed and that vigabatrin will be dispensed to patients with documentation of safe-use conditions. 3) Implementation system: Vigabatrin Sponsors will ensure that vigabatrin is only distributed to certified pharmacies by ensuring that the wholesale/distributors comply with the program requirements, which includes submission of distribution records of all vigabatrin shipments to the REMS program. Vigabatrin Sponsors will maintain a secure database of all certified pharmacies and patients enrolled in the REMS program. A REMS program call center and website will be maintained by Vigabatrin Sponsors in order to provide resources and support for all aspects of the REMS program. [3]
- B. To improve patient care and facilitate clinical research, the International League Against Epilepsy (ILAE) appointed a Task Force to formulate a consensus definition of drug resistant epilepsy. The following definition was formulated: Drug resistant epilepsy may be defined as failure of adequate trials of two tolerated and appropriately chosen and used antiepileptic drug (AED) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom. [4]

4 . References

1. Sabril Prescribing Information. Lundbeck. Deerfield, IL. May 2020.
2. Vigadrone Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. February 2020.
3. REMS@FDA: Vigabatrin Risk Evaluation and Mitigation Strategy (REMS) Program. U.S. Food and Drug Administration; Available at: <https://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=364>. Accessed February 15, 2021.

4. Kwan P, Arzimanoglou A, Berg AT, et al. Definition of drug resistant epilepsy: consensus proposal by the ad hoc Task Force of the ILAE Commission on Therapeutic Strategies. *Epilepsia*. 2010 Jun;51(6):1069-77.

Prior Authorization Guideline

Guideline Name	Sapropterin Products
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Kuvan (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.
Drug Name: Javygtor (sapropterin dihydrochloride)
Phenylketonuria Indicated to reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). It is to be used in conjunction with a Phe-restricted diet.

2 . Criteria

Product Name: Brand Kuvan, Brand Javygtor	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of phenylketonuria (PKU)</p> <p style="text-align: center;">AND</p> <p>2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to generic sapropterin</p>	

Product Name: Brand Kuvan, Brand Javygtor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]</p> <p style="text-align: center;">AND</p> <p>2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]</p>	

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

Product Name: Generic sapropterin	
Approval Length	2 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of phenylketonuria (PKU)	
AND	
2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]	
AND	
3 - Patient will have Phe blood levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response [E]	

Product Name: Generic sapropterin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline [B -D]	

AND

2 - Used in conjunction with a phenylalanine (Phe)-restricted diet [A]

AND

3 - Patient will continue to have blood Phe levels measured periodically during therapy [E]

3 . Endnotes

- A. All patients who are treating phenylketonuria (PKU) with sapropterin should also be treated with a phenylalanine (Phe) restricted diet [1].
- B. Sapropterin was evaluated in a phase III, randomized, placebo-controlled trial to determine its efficacy in reducing blood Phe concentration [2]. The primary endpoint was mean change from baseline in concentration of Phe in blood after 6 weeks. The mean age was 20 years. Results showed that after 6 weeks of therapy, patients who received sapropterin (n=41) had a decrease in mean blood Phe of 236 micromol/L, compared with a 3 micromol/L increase in the placebo group (n=47; p less than 0.0001).
- C. Patients should be evaluated for response to therapy after treatment with sapropterin at 20mg/kg per day for a period of one month [1]. The 2 month initial authorization duration allows for patients who start on 10mg/kg per day for the first month, to increase their dose to 20mg/kg per day for an additional month prior to evaluation of response.
- D. In clinical trials, response to therapy was defined as greater than or equal to 30% decrease in blood Phe from baseline [1]. The American College of Medical Genetics and Genomics guideline notes a significant decline in blood Phe is expected in sapropterin responders once treatment is started [3]. A reduction of 30% is most often cited in the literature as evidence of effective Phe reduction.
- E. Phe blood levels should be checked after one week of sapropterin treatment and periodically after that to assess blood Phe control [1].

4 . References

- 1. Kuvan prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. February 2021.
- 2. Levy HL, Milanowski A, Chakrapani A, et al. Efficacy of sapropterin dihydrochloride (tetrahydrobiopterin, 6R-BH4) for reduction of phenylalanine concentration in patients with phenylketonuria: a phase III randomised placebo-controlled study. *Lancet*. 2007;370(9586):504-10.
- 3. Vockley J, Andersson HC, Antshel KM, et al. Phenylalanine hydroxylase deficiency: diagnosis and management guideline. *Genet Med*. 2014 Feb;16(2):188-200.

4. Javygtor prescribing information. Dr. Reddys Laboratories Inc. Princeton, NJ. January 2022.

Prior Authorization Guideline

Guideline Name	Sarclisa (isatuximab-irfc)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Sarclisa (isatuximab-irfc)
Multiple Myeloma Indicated in combination with pomalidomide and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

2 . Criteria

Product Name: Sarclisa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of multiple myeloma	

AND

2 - Patient has received at least two prior treatment regimens which included both of the following:

- Lenalidomide
- A proteasome inhibitor (e.g., bortezomib, carfilzomib)

AND

3 - Used in combination with both of the following:

- Pomalidomide
- Dexamethasone

AND

4 - Prescribed by or in consultation with an oncologist/hematologist

Product Name: Sarclisa

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Sarclisa Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. March 2020.

Scemblix (asciminib)

Prior Authorization Guideline

Guideline Name	Scemblix (asciminib)
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Scemblix
Philadelphia chromosome-positive chronic myeloid leukemia Indicated for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs). Scemblix is also indicated for the treatment of Ph+CML in CP with the T315I mutation.

2 . Criteria

Product Name: Scemblix	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic myelogenous/myeloid leukemia (CML) [1, 2]

AND

2 - Disease is Philadelphia chromosome-positive (Ph+)

AND

3 - Disease is in chronic phase

AND

4 - One of the following:

4.1 Both of the following:

4.1.1 Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tassigna (nilotinib), Iclusig (ponatinib)]

AND

4.1.2 Prescribed medication will be dosed at a maximum of 80 mg per day

OR

4.2 Both of the following:

4.2.1 Disease is T315I mutation positive

AND

4.2.2 Prescribed medication will be dosed at a maximum of 400 mg per day

AND

5 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Scemblix	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Scemblix [prescribing information]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation. October 2021.
2. Scemblix. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Accessed December 3, 2021. <http://www.micromedexsolutions.com>.

Selzentry (maraviroc)

Prior Authorization Guideline

Guideline Name	Selzentry (maraviroc)
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Selzentry (maraviroc)
CCR5-tropic HIV-1 Indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in adults and pediatric patients weighing at least 2 kg. Limitations of Use: Selzentry is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

2 . Criteria

Product Name: Brand Selzentry tablets, generic maraviroc 150mg and 300mg tablets, Selzentry solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

1.1.3 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

3 . References

1. Selzentry prescribing information. ViiV Healthcare. Research Triangle Park, NC. November 2021.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Dec 2019; 1-378. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf>. Accessed September 24, 2021.

Prior Authorization Guideline

Guideline Name	SGLT2 Inhibitors
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Farxiga (dapagliflozin)
<p>Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. Limitations of Use: Farxiga is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Farxiga is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m². Farxiga is likely to be ineffective in this setting based upon its mechanism.</p> <p>Heart Failure Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction.</p> <p>Chronic Kidney Disease Indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of use: Farxiga is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Farxiga is not expected to be effective in these populations.</p>
Drug Name: Glyxambi (empagliflozin/linagliptin)
<p>Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of</p>

cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: Glyxambi is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Glyxambi has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Glyxambi. Glyxambi is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m². Glyxambi is likely to be ineffective in this setting based upon its mechanism of action.

Drug Name: Invokamet (canagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Invokamet XR (canagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Invokana (canagliflozin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of use: Invokana is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Invokana is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m². INVOKANA is likely to be ineffective in this setting based upon its mechanism of action.

Drug Name: Jardiance (empagliflozin)

Cardiovascular Disease Indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Jardiance is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Jardiance is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m². Jardiance is likely to be ineffective in this setting based upon its mechanism of action.

Heart Failure Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

Drug Name: Synjardy (empagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Synjardy is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Cardiovascular Disease Empagliflozin is indicated in adults with Type 2 diabetes mellitus to reduce the risk of cardiovascular death in adults with established cardiovascular disease.

Heart Failure Empagliflozin is indicated in adults with Type 2 diabetes mellitus to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. Limitations of use: Because of the metformin component, Synjardy is not recommended for use in patients with heart failure without Type 2 diabetes mellitus.

Drug Name: Synjardy XR (empagliflozin and metformin hydrochloride extended-release)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Synjardy is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Cardiovascular Disease Empagliflozin is indicated in adults with Type 2 diabetes mellitus to reduce the risk of cardiovascular death in adults with established cardiovascular disease.

Heart Failure Empagliflozin is indicated in adults with Type 2 diabetes mellitus to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. Limitations of use: Because of the metformin component, Synjardy is not recommended for use in patients with heart failure without Type 2 diabetes mellitus.

Drug Name: Xigduo XR (dapagliflozin/metformin XR)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated to reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD) or multiple cardiovascular (CV) risk factors. Limitation of use:

XIGDUO XR is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Heart Failure Dapagliflozin is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. Limitations of use: Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Chronic Kidney Disease Dapagliflozin is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of use: Xigduo XR is not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for kidney disease. Xigduo XR is not expected to be effective in these populations. Because of the metformin component, the use of XIGDUO XR is limited to adults with type 2 diabetes mellitus for all indications.

Drug Name: Trijardy XR (empagliflozin/linagliptin/metformin XR)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: Trijardy XR is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Trijardy XR Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy XR.

2 . Criteria

Product Name: Glyxambi, Synjardy, Synjardy XR, Trijardy XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p>	

AND

2 - Trial and failure of a minimum 90-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

Product Name: Invokamet, Invokamet XR, Invokana	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p>AND</p> <p>2 - One of the following:</p> <p>2.1 Trial and failure of a minimum 90-day supply, contraindication, or intolerance to one of the following generics:</p> <ul style="list-style-type: none">• metformin• metformin ER• glipizide-metformin• glyburide-metformin• pioglitazone-metformin <p>OR</p> <p>2.2 Patient has one of the following:</p>	

- History of atherosclerotic cardiovascular disease (ASCVD)
- High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)
- Established chronic kidney disease (CKD)
- Heart failure

AND

3 - Trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

- Farxiga
- Xigduo XR

AND

4 - Trial and failure of a minimum 90 day supply, or intolerance to one of the following:

- Glyxambi
- Jardiance
- Synjardy
- Synjardy XR
- Trijardy XR

Product Name: Farxiga	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction</p>	

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [10, 11]

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 90-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Farxiga is being used as initial therapy to treat diabetes in patients with concurrent HFrEF, ASCVD, or with multiple cardiovascular risk factors

OR

1.4 Diagnosis of chronic kidney disease

Product Name: Jardiance

Approval Length	12 month(s)
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Guideline Type	Step Therapy
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Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of type 2 diabetes mellitus

AND

1.1.2 Trial and failure of a minimum 90-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.2.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [10, 11]

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- sprinolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2.2 One of the following:

- Diagnosis of heart failure with preserved ejection fraction [12]
- Diagnosis of heart failure with mildly reduced ejection fraction

Product Name: Xigduo XR	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of heart failure (NYHA class II-IV) with reduced ejection fraction

AND

1.1.2 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following: [10, 11]

- captopril
- enalapril
- lisinopril
- quinapril
- ramipril
- fosinopril
- trandolapril
- perindopril
- candesartan
- valsartan
- losartan
- bisoprolol
- carvedilol IR/ER
- metoprolol succinate CR/XL
- spironolactone
- eplerenone
- Entresto (sacubitril-valsartan)

OR

1.2 Both of the following:

1.2.1 Diagnosis of type 2 diabetes mellitus

AND

1.2.2 Trial and failure of a minimum 90-day supply, contraindication, or intolerance to one of the following generics:

- metformin

- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

1.3 Diagnosis of chronic kidney disease

3 . References

1. Farxiga Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2021.
2. Glyxambi Prescribing Information. Boehringer Ingelheim. Ridgefield, CT. March 2022.
3. Invokana Prescribing Information. Janssen. Titusville, NJ. October 2022.
4. Invokamet Prescribing Information. Janssen. Titusville, NJ. October 2022.
5. Invokamet XR Prescribing information. Janssen Ortho, LLC. Titusville, NJ. October 2022.
6. Jardiance Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. March 2022.
7. Synjardy/Synjardy XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. May 2023.
8. Trijardy XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2021.
9. Xigduo XR Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2022.
10. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation*. 2017;136:e137–e161.
11. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction. *J Am Coll Cardiol*. 2021;77 (6): 772–810.
12. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *Journal of Cardiac Failure*. Published online April 2022.

Prior Authorization Guideline

Guideline Name	Short-Acting Bronchodilators
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Guideline Note:

Effective Date:	6/1/2022
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1 . Indications

Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)
Bronchospasm Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.
Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)
Bronchospasm Indicated the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.
Drug Name: Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol), Proair Digihaler (albuterol sulfate inhalation powder)
Bronchospasm Indicated for the treatment of or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.
Exercise-Induced Bronchospasm Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 . Criteria

Product Name: Proair Digihaler, Proair HFA, Proair Respiclick, Proventil HFA, Xopenex HFA, levalbuterol HFA, Ventolin HFA or Brand Albuterol HFA (Prasco manufacturer only, NDC 66993-0019-68)

Approval Length	12 Months
Guideline Type	Step Therapy

Approval Criteria

1 - Trial of generic albuterol HFA

3 . References

1. Proventil HFA Prescribing Information. Merck & Co. Inc. Whitehouse Station, NJ. September 2017.
2. Xopenex HFA Prescribing Information. Sunovion Pharmaceuticals Inc. Marlborough, MA. February 2017.
3. Ventolin HFA Prescribing Information. GalaxoSmithKline. Research Triangle Park, NC. March 2018.
4. Proair HFA Prescribing Information. Teva Respiratory, LLC. Frazer, PA. February 2019.
5. Proair Digihaler Prescribing Information. Teva Respiratory, LLC. Frazer, PA. December 2018.

Signifor (pasireotide)

Prior Authorization Guideline

Guideline Name	Signifor (pasireotide)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Signifor (pasireotide)
Cushing's disease Indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

2 . Criteria

Product Name: Signifor	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of endogenous Cushing's disease

AND

2 - One of the following:

2.1 Pituitary surgery has not been curative for the patient

OR

2.2 Patient is not a candidate for pituitary surgery

AND

3 - Prescribed by or in consultation with an endocrinologist

Product Name: Signifor

Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease)

3 . References

1. Signifor prescribing information. Recordati Rare Diseases Inc. Lebanon, NJ. March 2020.

Siklos (hydroxyurea)

Prior Authorization Guideline

Guideline Name	Siklos (hydroxyurea)
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Siklos (hydroxyurea)
Sickle Cell Anemia Indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises.

2 . Criteria

Product Name: Siklos	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of sickle cell anemia	

AND

2 - Patient has moderate to severe painful crises

AND

3 - Patient is 2 years of age or older

AND

4 - One of the following:

- Patient is less than 18 years of age
- Trial and failure, or intolerance to Droxia

3 . References

1. Siklos Prescribing Information. Addmedica, France. December 2021.

Siliq (brodalumab)

Prior Authorization Guideline

Guideline Name	Siliq (brodalumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Siliq (brodalumab)
Plaque Psoriasis Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies.

2 . Criteria

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - One of the following:

5.1 Both of the following:

5.1.1 Trial and failure, contraindication, or intolerance to THREE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Skyrizi (risankizumab)
- Stelara (ustekinumab)

- Tremfya (guselkumab)

AND

5.1.2 Trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

OR

5.2 For continuation of prior Siliq therapy, defined as no more than a 45-day gap in therapy

Product Name: Siliq	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction the body surface area (BSA) involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline 	

3 . References

1. Siliq Prescribing Information. Valeant Pharmaceuticals Int. Bridgewater, NJ. April 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Prior Authorization Guideline

Guideline Name	Simponi, Simponi Aria (golimumab)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Simponi (golimumab) - for subcutaneous use

Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Psoriatic Arthritis (PsA) Alone or in combination with methotrexate, indicated for the treatment of adult patients with active psoriatic arthritis.

Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.

Ulcerative Colitis (UC) Indicated in adult patients with moderately to severely active ulcerative colitis who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-mercaptopurine for: (1) inducing and maintaining clinical response, (2) improving endoscopic appearance of the mucosa during induction, (3) inducing clinical remission, and (4) achieving and sustaining clinical remission in induction responders.

Drug Name: Simponi Aria (golimumab) - for intravenous use

Rheumatoid Arthritis (RA) In combination with methotrexate, indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis.

Polyarticular Juvenile Idiopathic Arthritis (PJIA) Indicated for the treatment of active polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age and older.

Psoriatic Arthritis (PsA) Indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.

2 . Criteria

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active RA</p> <p style="text-align: center;">AND</p> <p>2 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [3, 4]:</p> <ul style="list-style-type: none">• methotrexate• leflunomide• sulfasalazine <p style="text-align: center;">AND</p> <p>3 - Used in combination with methotrexate</p> <p style="text-align: center;">AND</p>	

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria

Diagnosis	Rheumatoid Arthritis (RA)
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1-4]:

- Reduction in the total active (swollen and tender) joint count from baseline
- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

Product Name: Simponi Aria

Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
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Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of moderate to severely active PJIA

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [5]:

- leflunomide
- methotrexate

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [2, 5]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline 	

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active PsA</p> <p style="text-align: center;">AND</p>	

2 - One of the following [6]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 2, 6]:	
<ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline• Reduction in the body surface area (BSA) involvement from baseline	

Product Name: Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

3 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 2, 7]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [8, 9]:</p> <ul style="list-style-type: none"> • Greater than 6 stools per day • Frequent blood in the stools • Frequent urgency • Presence of ulcers • Abnormal lab values (e.g., hemoglobin, ESR, CRP) • Dependent on, or refractory to, corticosteroids <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)</p> <p style="text-align: center;">OR</p> <p>3.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies [1, 8, 9]</p> <ul style="list-style-type: none"> • 6-mercaptopurine • Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine) • Azathioprine • Corticosteroids (e.g., prednisone) <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a gastroenterologist</p>	

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 8, 9]:</p> <ul style="list-style-type: none"> Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline Reversal of high fecal output state 	

3 . References

1. Simponi Prescribing Information. Janssen Biotech Inc. Horsham, PA. September 2019.
2. Simponi Aria Prescribing Information. Janssen Biotech, Inc. Horsham, PA. February 2021.
3. Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
4. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
5. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
7. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.
8. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol.* 2019;114:384-413.
9. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol.* 2020;158:1450-1461.

Skyclarys (omaveloxolone)

Prior Authorization Guideline

Guideline Name	Skyclarys (omaveloxolone)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Skyclarys (omaveloxolone)
Friedreich's ataxia Indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older

2 . Criteria

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene	

AND

2 - Patient is 16 years of age or older

AND

3 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80

AND

4 - Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Neurogeneticist
- Physiatrist (Physical Medicine and Rehabilitation Specialist)

Product Name: Skyclarys	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	
AND	

2 - Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of less than or equal to 80 [A]

3 . Endnotes

- A. Patients enrolled in the trial were those with an mFARS score between 20 and 80. There is no evidence of benefit for patients with severe neurologic dysfunction with an mFARS score of greater than 80.

4 . References

1. Skyclarys Package Insert. Reata Pharmaceuticals, Inc. Plano, TX. March 2023.

Prior Authorization Guideline

Guideline Name	Skyrizi (risankizumab-rzaa)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Skyrizi SC (risankizumab-rzaa)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.
Psoriatic Arthritis (PsA) Indicated for the treatment of active psoriatic arthritis in adults.
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.
Drug Name: Skyrizi IV (risankizumab-rzaa)
Crohn's Disease (CD) Indicated for the treatment of moderately to severely active Crohn's disease in adults.

2 . Criteria

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis

Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [2]:</p> <ul style="list-style-type: none"> • Greater than or equal to 3% body surface area involvement • Severe scalp psoriasis • Palmoplantar (i.e., palms, soles), facial, or genital involvement <p style="text-align: center;">AND</p> <p>3 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:</p> <ul style="list-style-type: none"> • corticosteroids (e.g., betamethasone, clobetasol) • vitamin D analogs (e.g., calcitriol, calcipotriene) • tazarotene • calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • anthralin • coal tar <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a dermatologist</p>	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction the body surface area (BSA) involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline 	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis (PsA)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [4]:</p> <ul style="list-style-type: none"> • Actively inflamed joints • Dactylitis • Enthesitis • Axial disease • Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p>	

<ul style="list-style-type: none"> • Dermatologist • Rheumatologist 	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 150 mg	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline • Reduction in the body surface area (BSA) involvement from baseline 	
Notes	If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi IV	
Diagnosis	Crohn's Disease (CD)
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active Crohn's disease (CD)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [5, 6]:</p>	

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- Azathioprine
- Methotrexate
- Corticosteroid (e.g., prednisone)

AND

4 - Will be administered as an intravenous induction dose

AND

5 - Prescribed by or in consultation with a gastroenterologist

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderately to severely active Crohn's disease (CD)	

AND

2 - Will be used as a maintenance dose following the intravenous induction doses

AND

3 - Prescribed by or in consultation with a gastroenterologist

Notes

If patient meets criteria above, please approve at GPI-14

Product Name: Skyrizi SC 180 mg, 360 mg	
Diagnosis	Crohn's Disease (CD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5, 6]:	
<ul style="list-style-type: none">• Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline• Reversal of high fecal output state	
Notes	If patient meets criteria above, please approve at GPI-14

3 . References

1. Skyrizi Prescribing Information. AbbVie, Inc. North Chicago, IL. March 2023.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113:481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology.* 2021;160(7):2496-2508.

Soanz (torsemide)

Prior Authorization Guideline

Guideline Name	Soanz (torsemide)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Soanz (torsemide)
Edema Indicated in adults for the treatment of edema associated with heart failure or renal disease.

2 . Criteria

Product Name: Soanz	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of one of the following:	

- Heart failure
- Renal disease

AND

2 - Used for the treatment of edema

AND

3 - Trial and failure or intolerance to generic torsemide

AND

4 - Trial and failure or intolerance to ONE of the following generics:

- bumetanide
- furosemide

Product Name: Soanz	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., maintaining euvoemia)	

3 . References

1. Soanz Prescribing Information. Sarfez Pharmaceuticals, Inc. Vienna, VA. December 2021.

Prior Authorization Guideline

Guideline Name	Sodium Oxybate Containing Agents
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Xyrem (sodium oxybate) oral solution
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in patients 7 years of age and older with narcolepsy.
Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) Indicated for the treatment of excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
Drug Name: Lumryz (sodium oxybate) extended - release oral solution
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in adults with narcolepsy.
Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) Indicated for the treatment of excessive daytime sleepiness (EDS) in adults with narcolepsy.

2 . Criteria

Product Name: Xyrem, Brand Sodium Oxybate

Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, A, C, D]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (submission of medical records documenting study results required)</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms of cataplexy are present</p> <p style="text-align: center;">AND</p> <p>3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Neurologist • Psychiatrist • Sleep Medicine Specialist 	

Product Name: Xyrem, Brand Sodium Oxybate	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Xyrem, Brand Sodium Oxybate	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, B, C, E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (submission of medical records documenting study results required)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - BOTH of the following:

4.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to both of the following:

- Generic modafinil or armodafinil
- Sunosi

AND

4.2 ONE of the following

4.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

4.2.2 History of or potential for a substance use disorder

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Xyrem, Brand Sodium Oxybate	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Lumryz	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [2, 3, 12, A, C, D]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (submission of medical records documenting study results required)</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms of cataplexy are present</p> <p style="text-align: center;">AND</p> <p>3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication or intolerance to Wakix</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Neurologist• Psychiatrist	

- Sleep Medicine Specialist

Product Name: Lumryz	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - All of the following:</p> <p>1.1 ONE of the following:</p> <p>1.1.1 Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy</p> <p style="text-align: center;">OR</p> <p>1.1.2 Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy</p> <p style="text-align: center;">AND</p> <p>1.2 Trial and failure, contraindication or intolerance to Wakix</p>	

Product Name: Lumryz	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [2, 3, 12, B, C, E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study (submission of medical records documenting study results required)

AND

2 - Symptoms of cataplexy are absent

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - BOTH of the following:

4.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to TWO of the following:

- Generic modafinil or armodafinil
- Sunosi
- Wakix

AND

4.2 ONE of the following

4.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

4.2.2 History of or potential for a substance use disorder

AND

5 - Prescribed by or in consultation with one of the following:

- Neurologist
- Psychiatrist
- Sleep Medicine Specialist

Product Name: Lumryz	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy</p> <p style="text-align: center;">AND</p> <p>2 - BOTH of the following:</p> <p> 2.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight) or intolerance to TWO of the following:</p> <ul style="list-style-type: none">• Generic modafinil or armodafinil• Sunosi• Wakix <p style="text-align: center;">AND</p> <p> 2.2 ONE of the following</p> <p> 2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant</p>	

OR

2.2.2 History of or potential for a substance use disorder

3 . Endnotes

- A. International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [4-6]
- B. International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [4-6]
- C. Narcolepsy is often misdiagnosed. Treatment can often be given for the wrong reason if the patient has another condition with symptoms of excessive sleepiness. The diagnosis is the most important, and should be the focus in determining appropriate treatment. Both clinical symptoms and sleep study criteria (both daytime and nighttime tests) are needed to guide the diagnosis. [7]
- D. Xyrem is very effective and can be considered a first-line treatment for cataplexy in patients with narcolepsy (narcolepsy type 1). Antidepressants have mixed issues. Currently, there are no safety data with antidepressants for the treatment of cataplexy, and tricyclics and SSRIs cause a lot of side effects including anticholinergic effects,

sedation, impotence and EKG changes. Xyrem offers the advantage of treating cataplexy, and giving the patient more energy without the side effects compared to antidepressants. [7]

- E. Generally, modafinil or armodafinil is given first for excessive daytime sleepiness without cataplexy (narcolepsy type 2), followed by on-demand stimulants, then by Xyrem. There are no head-to-head trials with Xyrem, but anecdotal and clinical practice reports find that patients receive a similar response as with modafinil/armodafinil, but not as good as stimulants for excessive daytime sleepiness. [7]

4 . References

1. Xyrem Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. December 2020.
2. Morgenthaler TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine report. *Sleep*. 2007 Dec;30(12):1705-11.
3. Wise MS, Arand DL, Auger RR, et al. Treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine review. *Sleep*. 2007 Dec;30(12):1712-27.
4. International classification of sleep disorders. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.
5. Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. *CHEST*. 2014 Nov;146(5):1387-1394.
6. Scammell TE. Clinical features and diagnosis of narcolepsy. UpToDate Website. April 2021. www.uptodate.com. Accessed October 21, 2021.
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8. Sun, Eric. Narcolepsy. 2021 Feb. Available at <https://www.sleepfoundation.org/narcolepsy>. Accessed October 21, 2021.
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10. Maski, K., Trotti, L., et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. 2021;17(9):1895–1945. Available at <https://jcsm.aasm.org/doi/10.5664/jcsm.9326>. Accessed October 21, 2021.
11. Sodium Oxybate Prescribing Information. Hikma Pharmaceuticals, USA Inc. Berkeley Heights, NJ. October 2022.
12. Lumryz Prescribing Information. Avadel CNS Pharmaceuticals, LLC. Chesterfield, MO. May 2023.

Prior Authorization Guideline

Guideline Name	Soliris (eculizumab)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Soliris (eculizumab)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
Atypical Hemolytic Uremic Syndrome (aHUS) Indicated for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Limitations of Use: Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of adult patients with generalized Myasthenia Gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
Neuromyelitis Optica Spectrum Disorder (NMOSD) Indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2 . Criteria

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p style="padding-left: 20px;">3.1 Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">3.2 Prescribed medication is used for maintenance therapy and will not exceed 900 mg weekly at week 5, then 900 mg every 2 weeks thereafter</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed medication is used for maintenance therapy and will not exceed 900 mg every 2 weeks</p>	

Product Name: Soliris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS)</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p style="padding-left: 20px;">3.1 For patients 18 years of age and older:</p> <p style="padding-left: 40px;">3.1.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks</p>	

OR

3.1.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg weekly at week 5, then 1200 mg every 2 weeks thereafter

OR

3.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for dosing schedule)

AND

4 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Soliris

Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response (e.g., increase in mean platelet counts, hematologic normalization) to therapy

AND

2 - One of the following:

2.1 For patients 18 years of age and older, prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks

OR

2.2 For patients less than 18 years of age, dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for aHUS (refer to Table 1 in Background Section for MAINTENANCE dosing schedule)

Product Name: Soliris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2, 3]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Trial and failure, contraindication, or intolerance to one of the following:

- Ultomiris (ravulizumab)
- Vyvgart (efgartigimod)

AND

5 - One of the following:

5.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

OR

5.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Soliris

Diagnosis

Generalized Myasthenia Gravis (gMG)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks</p>	

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of neuromyelitis optica spectrum disorder (NMOSD)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is anti-aquaporin-4 (AQP4) antibody positive</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p style="padding-left: 20px;">3.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks</p>	

OR

3.2 Prescribed medication is used for maintenance therapy and will not exceed 1200 mg at week 5, then 1200 mg every 2 weeks thereafter

AND

4 - Prescribed by or in consultation with one of the following:

- Neurologist
- Ophthalmologist

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	
AND	
2 - Prescribed medication is used for maintenance therapy and will not exceed 1200 mg every 2 weeks	

3 . Background

Benefit/Coverage/Program Information

Table 1. Dosing Recommendations for Atypical Hemolytic Uremic Syndrome (aHUS) in Patients Less Than 18 Years of Age

Patient Body Weight	Induction Therapy	Maintenance Therapy
40 kg and over	900 mg weekly for 4 doses	1200 mg at week 5; Then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg weekly for 2 doses	900 mg at week 3; Then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg weekly for 2 doses	600 mg at week 3; Then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg weekly for 1 dose	300 mg at week 2; Then 300 mg every 3 weeks

4 . References

1. Soliris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. November 2020.
2. Howard JF Jr, Utsugisawa K, Benatar M, et al. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalised myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. *Lancet Neurol.* 2017;16(12):976-986.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology.* 2016;87(4):419-25.

Somatuline Depot (lanreotide)

Prior Authorization Guideline

Guideline Name	Somatuline Depot (lanreotide)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Somatuline Depot	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of acromegaly AND 2 - One of the following:	

2.1 Inadequate response to one of the following:

- Surgery
- Radiotherapy

OR

2.2 Not a candidate for one of the following:

- Surgery
- Radiotherapy

Product Name: Somatuline Depot	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to Somatuline Depot therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex	

Product Name: Somatuline Depot 120mg/0.5mL	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)	

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Somatuline Depot therapy	

Product Name: Somatuline Depot 120mg/0.5mL	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of carcinoid syndrome	

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

Product Name: Somatuline Depot 120mg/0.5mL	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to Somatuline Depot therapy	

2 . References

1. Somatuline Depot prescribing information. Ipsen Biopharmaceuticals, Inc. Basking Ridge, NJ. February 2018.

Somavert (pegvisomant)

Prior Authorization Guideline

Guideline Name	Somavert (pegvisomant)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Somavert (pegvisomant)
Acromegaly Indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.

2 . Criteria

Product Name: Somavert	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of acromegaly

AND

2 - One of the following: [2]

2.1 Inadequate response to one of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

OR

2.2 Not a candidate for all of the following:

- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

AND

3 - Trial and failure, contraindication, or intolerance to generic octreotide (a somatostatin analogue) [2]

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somavert	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy (such as biochemical control; decrease or normalization of IGF-1 levels)

3 . References

1. Somavert Prescribing Information. Pharmacia & Upjohn Company LLC. New York, NY. August 2021.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An endocrine society clinical practice guideline, J Clin Endocrinol Metab, 2014 Nov;99(11):3933-51. doi: 10.1210/jc.2014-2700. Epub 2014 Oct 30.

Sotyktu (deucravacitinib)

Prior Authorization Guideline

Guideline Name	Sotyktu (deucravacitinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Sotyktu (deucravacitinib)
Plaque Psoriasis (PsO) Indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Limitations of Use: Sotyktu is not recommended for use in combination with other potent immunosuppressants.

2 . Criteria

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
Approval Criteria	

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- At least 3% body surface area (BSA) involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Both of the following:

5.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Skyrizi (risankizumab-rzaa)
- Stelara (ustekinumab)

- Tremfya (guselkumab)

AND

5.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

AND

6 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine, biologic disease-modifying antirheumatic drugs [DMARDs])

Product Name: Sotyktu	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none"> • Reduction the body surface area (BSA) involvement from baseline • Improvement in symptoms (e.g., pruritus, inflammation) from baseline <p>AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming a minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:</p> <ul style="list-style-type: none"> • corticosteroids (e.g., betamethasone, clobetasol) • vitamin D analogs (e.g., calcitriol, calcipotriene) • tazarotene • calcineurin inhibitors (e.g., tacrolimus, pimecrolimus) • anthralin 	

- coal tar

AND

3 - Both of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to TWO of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Skyrizi (risankizumab-rzaa)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

AND

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Taltz (ixekizumab)

AND

4 - Not used in combination with other potent immunosuppressants (e.g., azathioprine, cyclosporine, biologic DMARDs)

3 . References

1. Sotyktu Prescribing Information. Bristol-Myers Squibb Co. Princeton, NJ. September 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Prior Authorization Guideline

Guideline Name	Sovaldi (sofosbuvir)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Sovaldi (sofosbuvir)
<p>Chronic Hepatitis C (CHC) ADULT PATIENTS: Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection as a component of a combination antiviral treatment regimen. - Genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis for use in combination with pegylated interferon and ribavirin. - Genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.</p> <p>PEDIATRIC PATIENTS: Indicated for the treatment of chronic HCV genotype 2 or 3 infection in pediatric patients 3 years of age and older without cirrhosis or with compensated cirrhosis for use in combination with ribavirin</p>

2 . Criteria

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1 or 4 - Sovaldi Plus Peginterferon Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1 or 4

AND

2 - Used in combination with peginterferon alfa and ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to **ONE** of the following:

- Epclusa (sofosbuvir/velpatasvir)

- Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 2 - Sovaldi Plus Ribavirin
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 2 infection</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with ribavirin</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious disease specialist • HIV specialist certified through the American Academy of HIV Medicine 	

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 3 - Sovaldi Plus Ribavirin
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Approval Length	24 Week(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3 infection

AND

2 - Used in combination with ribavirin

AND

3 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

AND

6 - One of the following:

6.1 Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to BOTH of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Sovaldi (sofosbuvir) therapy

Product Name: Sovaldi

Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Mavyret)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced treatment failure with Mavyret (glecaprevir/pibrentasvir) [2]</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious disease specialist • HIV specialist certified through the American Academy of HIV Medicine <p style="text-align: center;">AND</p> <p>5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)</p>	

Product Name: Sovaldi	
Diagnosis	Chronic Hepatitis C (without decompensation) - Genotype 1, 2, 3, 4, 5, or 6; Treatment-Experienced (Prior failure of Vosevi)
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

3 . References

1. Sovaldi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Spevigo (spesolimab-sbzo)

Prior Authorization Guideline

Guideline Name	Spevigo (spesolimab-sbzo)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Spevigo (spesolimab-sbzo)
Generalized Pustular Psoriasis (GPP) Indicated for the treatment of generalized pustular psoriasis (GPP) flares in adults.

2 . Criteria

Product Name: Spevigo	
Approval Length	14 Days [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of generalized pustular psoriasis (GPP)	

AND

2 - Patient has a moderate to severe GPP flare based on one of the following:

- Presence of fresh pustules (new appearance or worsening of pustules)
- At least 5% of body surface area (BSA) covered with erythema and the presence of pustules
- A Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3 (moderate) [B]
- GPPPGA pustulation sub score of at least 2 (mild)

AND

3 - Prescribed by or in consultation with a dermatologist

AND

4 - Patient has not already received two infusions of Spevigo for a single flare

3 . Endnotes

- A. Spevigo is administered as a single intravenous infusion. If GPP flare symptoms persist, an additional intravenous dose may be administered one week after the initial dose [1].
- B. The total Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) score ranges from 0 (clear) to 4 (severe) [1].

4 . References

1. Spevigo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. September 2022.

Prior Authorization Guideline

Guideline Name	Spravato (esketamine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Spravato (esketamine)
<p>Depression Indicated, in conjunction with an oral antidepressant, for the treatment of: - Treatment-resistant depression (TRD) in adults - Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior. Limitations of Use: The effectiveness of Spravato in preventing suicide or in reducing suicidal ideation or behavior has not been demonstrated. Use of Spravato does not preclude the need for hospitalization if clinically warranted, even if patients experience improvement after an initial dose of Spravato. Spravato is not approved as an anesthetic agent. The safety and effectiveness of Spravato as an anesthetic agent have not been established.</p>

2 . Criteria

Product Name: Spravato	
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of major depressive disorder (treatment-resistant)

AND

1.1.2 Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode [1-5, A, B]

OR

1.2 Both of the following:

1.2.1 Diagnosis of major depressive disorder

AND

1.2.2 Patient has both of the following:

- Depressive symptoms
- Acute suicidal ideation or behavior

AND

2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)

AND

3 - Prescribed by or in consultation with a psychiatrist

Product Name: Spravato	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline)</p>	

3 . Endnotes

- A. According to the American Psychiatric Association, generally, 4–8 weeks of treatment are needed before concluding that a patient is partially responsive or unresponsive to a specific intervention. [2]
- B. Per clinical consults with psychiatrists: A trial of antidepressants should include different classes (mechanisms of action) when defining treatment resistance. [4-5]

4 . References

1. Spravato Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. July 2020.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder (3rd Edition). October 2010. Available at: https://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf. Accessed August 18, 2020.
3. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163(11):1905-17.
4. Per clinical consult with psychiatrist, April 25, 2019.
5. Per clinical consult with psychiatrist, April 18, 2019.

Sprycel (dasatinib)

Prior Authorization Guideline

Guideline Name	Sprycel (dasatinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Sprycel (dasatinib)
<p>Newly diagnosed Chronic Myeloid Leukemia Indicated for the treatment of adults with newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.</p> <p>Resistant or intolerant Chronic Myeloid Leukemia Indicated for the treatment of adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.</p> <p>Acute Lymphoblastic Leukemia (ALL) Indicated for the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.</p> <p>Pediatric ALL Indicated for the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy.</p> <p>Pediatric Patients with Ph+ CML Indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase.</p>

2 . Criteria

Product Name: Sprycel	
Diagnosis	Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Ph+/BCR ABL acute lymphoblastic leukemia (ALL)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist and/or hematologist</p>	

Product Name: Sprycel	
Diagnosis	Ph+/BCR ABL Acute Lymphoblastic Leukemia/Acute Lymphoblastic Lymphoma (ALL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Sprycel	
Diagnosis	Ph+/BCR ABL Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL chronic myelogenous/myeloid leukemia (CML)

AND

2 - Prescribed by or in consultation with an oncologist and/or hematologist

Product Name: Sprycel

Diagnosis	Ph+/BCR ABL Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. According to National Comprehensive Cancer Network (NCCN) recommendations, imatinib, dasatinib, bosutinib, and nilotinib are first-line therapies for chronic myelogenous/myeloid leukemia. In settings where all 4 agents are appropriate as a first-line option, a step through any of the 4 products is inappropriate. [2]
- B. According to NCCN recommendations, patients with disease that is resistant to first-line imatinib should be treated with nilotinib, dasatinib, or bosutinib in the second-line setting, taking into account BCR::ABL1 kinase domain mutation status. Patients with disease that is resistant to first-line treatment with bosutinib, nilotinib, or dasatinib could be treated with an alternate TKI (other than imatinib) in the second-line setting, taking into account BCR::ABL1 kinase domain mutation status. Dasatinib and nilotinib are effective against a majority of mutations resistant to imatinib, except for the T315I mutation. Consider clinical trial, asciminib, ponatinib, omacetaxine, or hematopoietic cell transplantation (HCT) for patients with a T315I mutation. [2]

4 . References

1. Sprycel [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; June 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myeloid Leukemia v.1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed January 9, 2023.

Prior Authorization Guideline

Guideline Name	State Mandate Reference Document
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Guideline Note:

Effective Date:	1/5/2024
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Note:

Apply State Guidelines to these CAGs only: SWPACA, SWPFCHACA, SWPBSWACA, SWPBSWHP (excluding account code HMOLG00011), SWPBSWIC, SWPBSWCP

1 . Criteria

Guideline Type	
Administrative	
Approval Criteria	
1 - The following mandates apply to Texas:	
1.1 Effective 1/1/2018, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one	

prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, and if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or cause harm to the patient, based on medical necessity.

OR

1.2 Effective 1/1/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

1.3 Effective 1/1/2024, for a patient who is 18 years of age or older, any step therapy requirements for a drug used to treat serious mental illness, may not require:

- For initial coverage, that a patient fails or prove a history of failure to more than one drug (excluding the generic or pharmaceutical equivalent of the prescribed drug).
- For continued coverage, that a patient fails or prove a history of failure of any drugs other than the generic or pharmaceutical equivalent if it is added to the plan's drug formulary.

2 . Background

Benefit/Coverage/Program Information

Background:

This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations.

Additional Clinical Rules:

- Applicable clinical programs will apply.

Stelara (ustekinumab)

Prior Authorization Guideline

Guideline Name	Stelara (ustekinumab)
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Guideline Note:

Effective Date:	5/15/2023
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1 . Indications

Drug Name: Stelara SC (ustekinumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Psoriatic Arthritis (PsA) Indicated for the treatment of patients 6 years or older with active psoriatic arthritis.
Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.
Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.
Drug Name: Stelara IV (ustekinumab)
Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease.
Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

2 . Criteria

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Plaque Psoriasis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [2]:</p> <ul style="list-style-type: none">• Greater than or equal to 3% body surface area involvement• Severe scalp psoriasis• Palmoplantar (i.e., palms, soles), facial, or genital involvement <p style="text-align: center;">AND</p> <p>3 - Patient is 6 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:</p> <ul style="list-style-type: none">• corticosteroids (e.g., betamethasone, clobetasol)• vitamin D analogs (e.g., calcitriol, calcipotriene)• tazarotene• calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)• anthralin• coal tar <p style="text-align: center;">AND</p>	

5 - Prescribed by or in consultation with a dermatologist

Notes

*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC 90 mg/1 mL

Diagnosis | Plaque Psoriasis

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient's weight is greater than 100 kg (220 lbs)

AND

4 - Patient is 6 years of age or older

AND

5 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

6 - Prescribed by or in consultation with a dermatologist

Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriasis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)
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Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:</p> <ul style="list-style-type: none">• Reduction the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

Product Name: Stelara SC 45 mg/0.5 mL	
Diagnosis	Psoriatic arthritis
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [4]:</p> <ul style="list-style-type: none"> • Actively inflamed joints • Dactylitis • Enthesitis • Axial disease • Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Patient is 6 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Rheumatologist 	
Notes	<p>*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)</p>

Product Name: Stelara SC 90 mg/1 mL

Diagnosis Psoriatic arthritis

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis

AND

2 - One of the following [4]:

- Actively inflamed joints
- Dactylitis
- Enthesitis
- Axial disease
- Active skin and/or nail involvement

AND

3 - Diagnosis of co-existent moderate to severe psoriasis [1, 4]

AND

4 - Patient's weight is greater than 100 kg (220 lbs)

AND

5 - Patient is 6 years of age or older

AND

6 - Prescribed by or in consultation with one of the following:

<ul style="list-style-type: none"> • Dermatologist • Rheumatologist 	
Notes	*Approval Duration: 6 months. **QL Override (For new starts only): For psoriatic arthritis, please enter 2 PAs as follows: First PA: Approve one syringe or vial per 28 days for the two months with a fill count of 2; Second PA: Approve one syringe or vial per 56 days (no overrides needed) for the remaining 4 months. (Stelara is hard-coded with a quantity of one prefilled syringe/vial per 56 days; 0.5 mL per 45 mg vial or syringe and 1 mL per 90 mg syringe)

Product Name: Stelara SC	
Diagnosis	Psoriatic arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]:</p> <ul style="list-style-type: none"> • Reduction in the total active (swollen and tender) joint count from baseline • Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline • Reduction in the body surface area (BSA) involvement from baseline 	

Product Name: Stelara IV	
Diagnosis	Crohn's Disease
Approval Length	1 Time(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active Crohn's disease</p>	

AND

2 - One of the following [5, 6]:

- Frequent diarrhea and abdominal pain
- At least 10% weight loss
- Complications such as obstruction, fever, abdominal mass
- Abnormal lab values (e.g., C-reactive protein [CRP])
- CD Activity Index (CAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [5, 6]:

- 6-mercaptopurine
- azathioprine
- corticosteroids (e.g., prednisone)
- methotrexate

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's disease:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active Crohn's disease</p> <p style="text-align: center;">AND</p> <p>2 - Will be used as a maintenance dose following the intravenous induction dose</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a gastroenterologist</p>	

Product Name: Stelara IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [7, 8]:</p> <ul style="list-style-type: none"> • Greater than 6 stools per day • Frequent blood in the stools 	

- Frequent urgency
- Presence of ulcers
- Abnormal lab values (e.g., hemoglobin, ESR, CRP)
- Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to treatment with at least ONE of the following [7, 8]:

- Corticosteroid (e.g., prednisone)
- 6-mercaptopurine
- Azathioprine
- Aminosalicylates (e.g., mesalamine, olsalazine, sulfasalazine)

AND

4 - Stelara is to be administered as an intravenous induction dose

AND

5 - Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for ulcerative colitis:

- 260 mg for patients weighing 55 kg or less
- 390 mg for patients weighing more than 55 kg to 85 kg
- 520 mg for patients weighing more than 85 kg

AND

6 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - Will be used as a maintenance dose following the intravenous induction dose

AND

3 - Prescribed by or in consultation with a gastroenterologist

Product Name: Stelara SC	
Diagnosis	Crohn's Disease and Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:	
<ul style="list-style-type: none">• Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline• Reversal of high fecal output state	

3 . References

1. Stelara prescribing information. Janssen Biotech, Inc. Horsham PA. August 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.

3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021;84:432-70.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113:481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology*. 2021;160(7):2496-2508.
7. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114:384-413.
8. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol*. 2020;158:1450-1461.

Prior Authorization Guideline

Guideline Name	Stelara Quantity Limit Exception
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Stelara 90 mg	
Diagnosis	Crohn's disease or Ulcerative Colitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Administrative
Approval Criteria 1 - Diagnosis of Crohn's disease or Ulcerative colitis AND 2 - Both of the following:	

2.1 Patient is currently receiving the FDA-approved dose of the maintenance dosing regimen

AND

2.2 The maximum doses specified under the quantity restriction have been tried for at least 6 months and been deemed ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:

3.1 A decreased dosing interval is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 A decreased dosing interval is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

OR

3.3 Published clinical trial data has been submitted supporting non-FDA approved dosing regimen

OR

3.4 For continuation of prior Stelara therapy at a dosing interval less than the FDA-approved dose, for a minimum of 6 months, with a positive clinical response to decreased interval (e.g., recapture of clinical response, clinically significant decrease in biomarkers, discontinuation of corticosteroid therapy, clinically significant improvement in symptoms)

Product Name: Stelara 90 mg

Diagnosis

Crohn's disease or Ulcerative Colitis

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to decreased interval (e.g., recapture of clinical response, clinically significant decrease in biomarkers, discontinuation of corticosteroid therapy, clinically significant improvement in symptoms)</p>	

2 . Background

Benefit/Coverage/Program Information
<p>Quantity Limit</p> <p>These products are subject to a standard quantity limit. The quantity limit may vary from the standard limit based upon plan-specific benefit design. Please refer to your benefit materials.</p>

3 . References

1. Stelara prescribing information. Janssen Biotech, Inc. Horsham, PA. March 2020.

Prior Authorization Guideline

Guideline Name	Stivarga (regorafenib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Stivarga (regorafenib)
Metastatic Colorectal Cancer (mCRC) Indicated for the treatment of patients with metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF therapy, and, if RAS wild- type, an anti-EGFR therapy.
Gastrointestinal Stromal Tumor (GIST) Indicated for the treatment of patients with locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and sunitinib malate.
Hepatocellular Carcinoma (HCC) Indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.

2 . Criteria

Product Name: Stivarga	
Diagnosis	Metastatic Colorectal Cancer (mCRC) [1,2]
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic colorectal cancer (mCRC)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Gastrointestinal Stromal Tumor (GIST)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Locally advanced • Unresectable • Metastatic <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Stivarga	
Diagnosis	Hepatocellular Carcinoma (HCC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hepatocellular carcinoma (HCC)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Oncologist • Hepatologist • Gastroenterologist 	

Product Name: Stivarga	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Stivarga Prescribing Information. Bayer HealthCare Pharmaceuticals Inc., December 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed April 19, 2022.

Strensiq (asfotase alfa)

Prior Authorization Guideline

Guideline Name	Strensiq (asfotase alfa)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Strensiq (asfotase alfa)
Perinatal/infantile- and juvenile-onset hypophosphatasia (HPP) Indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

2 . Criteria

Product Name: Strensiq*	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Submission of medical records (e.g., chart notes) documenting all of the following:	

1.1 One of the following diagnoses:

- Perinatal/infantile-onset hypophosphatasia (HPP)
- Juvenile-onset hypophosphatasia (HPP)

AND

1.2 Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures) [A-D; 1, 7-9]

AND

1.3 Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, craniosynostosis, non-traumatic fractures, osteoporosis or low bone mineral content for age [as detected by DEXA]) [A-D; 1, 7-9]

AND

1.4 One of the following: [F-G; 2-6, 8]

1.4.1 Both of the following:

1.4.1.1 Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range

AND

1.4.1.2 Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

OR

1.4.2 Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing

AND

2 - Prescribed by a specialist experienced in the treatment of inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist) [H; 2-6]

AND

3 - Requested dose will not exceed the following: [H,1] (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)

- 9 mg/kg per week for perinatal/infantile-onset HPP
- 6 mg/kg per week for juvenile-onset HPP

AND

4 - If patient weighs less than 40 kg, the 80 mg/0.8mL vial will not be approved (patient's weight must be provided)

Notes

*If approved, approve auth at GPI-14 level. If the 80mg strength is requested: For patient 40 to 74 kg, approve 12 vials (9.6 mL) per 28 days for 80 mg/0.8 mL vials. For patient 75 to 119 kg, approve 24 vials (19.2 mL) per 28 days for the 80 mg/0.8 mL vials. For patients greater than equal to 120 kg, approve 36 vials (28.8 mL) per 28 days for the 80 mg/0.8 mL vials.

Product Name: Strensiq*

Approval Length

9 month(s)

Therapy Stage

Reauthorization

Guideline Type

Prior Authorization

Approval Criteria

1 - The patient has responded to treatment with Strensiq as evidenced by one of the following: [1, 7-9]

- Improvement and/or stabilization of clinical signs and/or symptoms of hypophosphatasia (e.g., respiratory status [ventilator free survival], growth) or radiographic findings (e.g., skeletal manifestations)
- Clinically relevant decrease from baseline in tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPI level])

AND

2 - Prescribed by a specialist experienced in the treatment of inborn errors of metabolism (e.g., endocrinologist, rheumatologist, geneticist, orthopedist) [H, 2-6]

AND

3 - Requested dose will not exceed the following: [H, 1] (Note to prescriber: Three times a week dosing leads to less waste and may lead to less injection site reactions compared to six times a week dosing)

- 9 mg/kg per week for perinatal/infantile-onset HPP
- 6 mg/kg per week for juvenile-onset HPP

AND

4 - If patient weighs less than 40 kg, the 80 mg/0.8mL vial will not be approved (patient's weight must be provided)

Notes	*If approved, approve auth at GPI-14 level. If the 80mg strength is requested: For patient 40 to 74 kg, approve 12 vials (9.6 mL) per 28 days for 80 mg/0.8 mL vials. For patient 75 to 119 kg, approve 24 vials (19.2 mL) per 28 days for the 80 mg/0.8 mL vials. For patients greater than equal to 120 kg, approve 36 vials (28.8 mL) per 28 days for the 80 mg/0.8 mL vials.
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Product Name: Strensiq	
Guideline Type	Quantity Limit*
Approval Criteria	

1 - For the 80mg/0.8mL vial, requests for additional quantity will not be approved	
Notes	*Note: Requests will be denied off-label.

3 . Endnotes

- A. Study 1 was a 24-week prospective single-arm trial in 11 patients, 7/11(64%) were female and 10/11(91%) were white, aged 3 weeks to 39.5 months with severe perinatal/infantile-onset HPP. Severe perinatal/infantile onset HPP was defined as biochemical, medical history and radiographic evidence of HPP as well as the presence of any of the following: rachitic chest deformity, vitamin B6 dependent seizures, or failure to thrive.[1]
- B. HPP is diagnosed by identifying its symptoms and complications beginning with a detailed patient history. HPP signs are revealed by a thorough clinical examination, and supported by routine x-rays and various laboratory tests including biochemical studies. [8]
- C. The clinical review team concluded that the totality of evidence, including growth, radiographic, and histomorphometric data collected in both populations and survival data collected in the perinatal/infantile-onset population, were sufficient to make a favorable medical risk benefit determination for approval for the juvenile-onset indication. [7]
- D. Clinical course Perinatal-onset HPP typically is diagnosed on prenatal ultrasound examination which demonstrates unmineralized or hypomineralized bone. As noted earlier, the lethal perinatal form results in stillbirth or early neonatal death secondary to pulmonary insufficiency caused by chest wall deformities (flail chest). Other clinical features may include fever, anemia, failure to thrive, irritability, apnea and bradycardia, intracranial hemorrhage and pyridoxine-dependent seizures. The benign perinatal form clinically resembles other milder forms of HPP. Infantile-onset HPP presents before age six months of age, with infants developing clinical signs and symptoms of rickets, including growth failure, hypotonia, bowing of long bones, and rachitic changes of the ribs. Other clinical hallmarks are wide fontanels (actually hypomineralized skull bone) and craniosynostosis. Other skull deformities may include hypertelorism and brachycephaly. Infantile-onset HPP patients are at increased risk of pneumonia due to flail chest In juvenile-onset HPP (also termed as childhood HPP), premature loss of the primary teeth (prior to age 5 years) is a major clinical hallmark of disease. Radiographic evidence of dental hypoplasia may precede radiographic evidence of skeletal disease. Patients who develop rickets may have delayed walking, gait abnormalities (waddling gait) and short stature. Other complications include pathologic fractures, most commonly involving the metaphysis, and static myopathy. Patient may also experience bone pain and stiffness. Some patients may improve spontaneously during puberty, with recurrence of skeletal symptoms during adulthood. As in infantile-onset HPP, patients with juvenile-onset HPP may develop nephrocalcinosis. Dental involvement of secondary dentition is generally less severe Adult-onset HPP usually presents during middle age, with about 50% of patients having a history of rickets and or premature dental loss during childhood. The chief clinical features of adult-onset HPP are recurrent stress fractures and femoral pseudofractures (areas of osteomalacia). Patients also may experience hip or thigh pain (secondary to femoral pseudofractures) and may develop chondrocalcinosis [7, 9]

- E. HPP is a rare metabolic disease characterized by low serum alkaline-phosphatase activity which results in bone mineralization defects and various systemic complications [2, 6] The disease arises from a genetic mutation within the tissue-nonspecific isozyme of alkaline phosphatase (TNSALP). The mutation results in a loss of function which leads to an accumulation of TNSALP substrates (e.g., inorganic pyrophosphate and pyridoxal 5'-phosphate (PLP)). Given the complexities and rarity of the condition, the criteria requires the medication to be prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, this aims to ensure proper diagnosis.
- F. HPP is caused by mutations in the ALPL gene. This is the only gene that causes HPP. The ALPL gene creates (encodes) a type of protein called an enzyme named TNSALP. Enzymes are specialized proteins that break down specific chemicals in the body. TNSALP is essential for the proper development and health of bones and teeth, and is abundant in the skeleton, liver, and kidneys. Mutations in the ALPL gene lower the activity of TNSALP, in turn leading to accumulation of phosphoethanolamine (PEA), pyridoxal 5'-phosphate (PLP), and inorganic pyrophosphate (PPI). [8]
- G. HPP is a rare metabolic disease characterized by low serum alkaline-phosphatase activity which results in bone mineralization defects and various systemic complications [2, 6] The disease arises from a genetic mutation within the tissue-nonspecific isozyme of alkaline phosphatase (TNSALP). The mutation results in a loss of function which leads to an accumulation of TNSALP substrates (e.g., inorganic pyrophosphate and pyridoxal 5'-phosphate (PLP)). Given the complexities and rarity of the condition, the criteria requires the medication to be prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, this aims to ensure proper diagnosis.
- H. The 80 mg/0.8 mL vial should not be used in patients weighing less than 40 kg, as the systemic exposure of the drug is lower than that achieved within the lower strengths. Use in these patients could result in inadequate exposure and poor treatment outcomes. [1]

4 . References

1. Strensiq prescribing information, Alexion Pharmaceuticals. Cheshire, CT. June 2020.
2. Hickman-Simmons, Jill. Best Practices in: Recognizing and Diagnosing Hypophosphatasia. Clinical Endocrinology News. November 2013. Available at: www.clinicalendocrinologynews.com/resources/best-practices.html. Accessed June 15, 2020.
3. Hofmann C, Rockman-greenberg C, Harmatz P, Moseley S, Odrijin T, Liese J. Improvement in bone manifestations and respiratory status in infants and young children with HPP treated with asfotase alfa: An update on the ENB-010-10 trial. In: Oral Presentation Presented at the 7th International Conference on Children's Bone Health. 27-30 June 2015. Salzburg, Austria.
4. Madson KL, Rockman-Greenberg C, Melian A, et al. Asfotase alfa: long-term safety and efficacy in children with hypophosphatasia. Poster presented at the Pediatric Academic Societies and Asian Society for Pediatric Research Joint Meeting; May 3-6, 2014; Vancouver, Canada.
5. Rockman-Greenberg C, Vockley J, Harmatz P, et al. Asfotase alfa improves skeletal mineralization and respiratory function in infants and young children with

hypophosphatasia: results from up to 12 months' treatment. Poster presented at the 2014 ACMG Annual Meeting; March 25-29, 2014; Nashville, TN.

6. Whyte MP, Greenberg CR, Salman N, et al. Enzyme-replacement therapy in life-threatening hypophosphatasia. *N Engl J Med*. 2012; 366(10):904-913.
7. Epps, C. Center for Drug Evaluation and Research Application Number: 125513ORIG1S000 Medical Review(s). 2015 October. Available at [HTTPS://WWW.ACCESSDATA.FDA.GOV/DRUGSATFDA_DOCS/NDA/2015/125513ORIG1S000MEDR.PDF](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125513ORIG1S000MEDR.pdf). Accessed October 4, 2021.
8. Whyte, M. Hypophosphatasia. NORD- National Organization for Rare Disorders. Available at <https://rarediseases.org/rare-diseases/hypophosphatasia/>. Accessed October 4, 2021.
9. Orimo, H. Pathophysiology of hypophosphatasia and the potential role of asfotase alfa. *Ther Clin Risk Manag*. 2016; 12: 777–786. Available at doi: 10.2147/TCRM.S87956. Accessed October 22, 2021

Prior Authorization Guideline

Guideline Name	Stromectol (ivermectin) tablets
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Stromectol (ivermectin)
<p>Strongyloidiasis of the intestinal tract Indicated for the treatment of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite <i>Strongyloides stercoralis</i>. This indication is based on clinical studies of both comparative and open-label designs, in which 64-100% of infected patients were cured following a single 200-mcg/kg dose of ivermectin.</p> <p>Onchocerciasis Indicated for the treatment of onchocerciasis due to the nematode parasite <i>Onchocerca volvulus</i>. This indication is based on randomized, double-blind, placebo-controlled and comparative studies conducted in 1427 patients in onchocerciasis-endemic areas of West Africa. The comparative studies used diethylcarbamazine citrate (DEC-C). NOTE: STROMECTOL has no activity against adult <i>Onchocerca volvulus</i> parasites. The adult parasites reside in subcutaneous nodules which are infrequently palpable. Surgical excision of these nodules (nodulectomy) may be considered in the management of patients with onchocerciasis, since this procedure will eliminate the microfilariae-producing adult parasites.</p>

2 . Criteria

Product Name: Stromectol

Diagnosis	Strongyloidiasis of the intestinal tract
Approval Length	One time approval
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite <i>Strongyloides stercoralis</i></p>	

Product Name: Stromectol	
Diagnosis	Onchocerciasis
Approval Length	6 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of onchocerciasis due to the nematode parasite <i>Onchocerca volvulus</i></p>	

Product Name: Stromectol	
Diagnosis	COVID-19
Approval Length	N/A - Requests for non-approvable diagnoses should not be approved
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - The request for Stromectol (ivermectin) for the treatment or prevention of COVID-19 infection is not authorized and will not be approved.</p>	

3 . References

1. Stromectol prescribing information. Merck & Co., Inc., Whitehouse Station, NJ. November 2020.

Prior Authorization Guideline

Guideline Name	Sublingual Allergen Immunotherapy Products (Grastek, Odactra, Oralair, Ragwitek)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Grastek (Timothy Grass Pollen Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens. Grastek is approved for use in persons 5 through 65 years of age. Grastek is not indicated for the immediate relief of allergic symptoms.
Drug Name: Odactra (House Dust Mite [Dermatophagoides farinae and Dermatophagoides pteronyssinus] Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or by positive skin testing to licensed house dust mite allergen extracts. Odactra is approved for use in persons 12 through 65 years of age. Odactra is not indicated for the immediate relief of allergic symptoms.
Drug Name: Oralair (Sweet Vernal, Orchard, Perennial Rye, Timothy, and Kentucky Blue Grass Mixed Pollens Allergen Extract)
Allergic Rhinitis Indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis with or without conjunctivitis confirmed by positive skin test or in vitro testing

for pollen-specific IgE antibodies for any of the five grass species contained in this product. Oralair is approved for use in persons 5 through 65 years of age. Oralair is not indicated for the immediate relief of allergy symptoms.

Drug Name: Ragwitek (Short Ragweed Pollen Allergen Extract)

Allergic Rhinitis Indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for short ragweed pollen. Ragwitek is approved for use in persons 5 through 65 years of age. Ragwitek is not indicated for the immediate relief of allergic symptoms.

2 . Criteria

Product Name: Grastek	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of grass pollen-induced allergic rhinitis</p> <p style="text-align: center;">AND</p> <p>2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to Timothy Grass or cross-reactive grass pollens</p> <p style="text-align: center;">AND</p> <p>3 - Treatment will be initiated 3 months before the expected onset of the grass pollen season</p> <p style="text-align: center;">AND</p> <p>4 - Patient is 5 to 65 years of age</p>	

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)
- An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Product Name: Odactra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of house dust mite (HDM)-induced allergic rhinitis	
AND	
2 - Positive in vitro testing for IgE antibodies to Dermatophagoides farinae or Dermatophagoides pteronyssinus house dust mites, or skin testing to licensed house dust mite allergen extracts	
AND	
3 - Patient is 12 to 65 years of age	

AND

4 - Trial and failure, contraindication, or intolerance to both of the following:

- An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)
- An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

5 - Prescribed by or in consultation with an allergist or immunologist

Product Name: Oralair	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of grass pollen-induced allergic rhinitis	
AND	
2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to any of the five grass species including sweet vernal, orchard, perennial rye, timothy or kentucky blue grass mixed pollens	
AND	
3 - Treatment will be initiated 4 months before the expected onset of the grass pollen season	

AND

4 - Patient is 5 to 65 years of age

AND

5 - Trial and failure, contraindication, or intolerance to both of the following:

- An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)
- An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Notes

ORALAIR Child Starter Packs/Sample Kits will only be approved for children less than 18 years of age

Product Name: Ragwitek

Approval Length | 12 month(s)

Therapy Stage | Initial Authorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Diagnosis of short ragweed pollen-induced allergic rhinitis

AND

2 - Patient has a positive skin test or in vitro test for pollen-specific IgE antibodies to short ragweed pollen

AND

3 - Treatment will be initiated 3 months before the expected onset of the ragweed pollen season

AND

4 - Patient is 5 to 65 years of age

AND

5 - Trial and failure, contraindication, or intolerance both of the following:

- An intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, flunisolide nasal spray)
- An antihistamine (e.g., cetirizine, loratadine, azelastine nasal spray, olapatadine nasal spray)

AND

6 - Prescribed by or in consultation with an allergist or immunologist

Product Name: Grastek, Odactra, Oralair, Ragwitek

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Patient has experienced improvement in the symptoms of their allergic rhinitis

OR

1.2 Patient has experienced a decrease in the number of medications needed to control allergy symptoms

3 . References

1. Grastek Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. August 2022.
2. Oralair Prescribing Information. GREER Laboratories, Inc. Lenoir, NC. December 2022.
3. Ragwitek Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. September 2022.
4. Odactra Prescribing Information. Catalent Pharma Solutions Limited. Swindon, UK. January 2023.

Prior Authorization Guideline

Guideline Name	Sucraid (sacrosidase) Oral Solution
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Sucraid (sacrosidase) Oral Solution
Congenital Sucrase-Isomaltase Deficiency (CSID) Indicated as oral replacement therapy of the genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency (CSID).

2 . Criteria

Product Name: Sucraid	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID])

AND

2 - Disease is confirmed by ONE of the following: [1, 2]

- Disaccharidase assay via a small bowel biopsy
- Carbon -13 sucrose breath test
- Molecular genetic testing confirms mutation in the SI gene
- Stool pH less than 6, an increase in breath hydrogen of greater than 10 parts-per-million (ppm) when challenged with sucrose after fasting and a negative lactose breath test

AND

3 - Prescribed by or in consultation with ONE of the following:

- Gastroenterologist
- Geneticist

Product Name: Sucraid	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., decrease in symptoms of abdominal pain, cramps, bloating or gas; decrease in number and frequency of stools per day)	

3 . References

1. Sucraid Prescribing Information. QOL Medical, LLC. Vero Beach, FL. May 2022.

2. Congenital Sucrase-Isomaltase Deficiency (CSID). International Foundation for Gastrointestinal Disorders. Available at <https://iffgd.org/gi-disorders/congenital-sucrase-isomaltase-deficiency-csid/>. Accessed October 24, 2022.
3. Smith, H., Romero, B., et al. The patient journey to diagnosis and treatment of congenital sucrase-isomaltase deficiency. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8298246/>. Accessed October 24, 2022.
4. Chey, W., Cash, B., et al. Congenital Sucrase-Isomaltase Deficiency: What, When, and How? *Gastroenterology and Hepatology*. October 2020. Available at <https://www.gastroenterologyandhepatology.net/files/2020/10/gh1020sup5-1.pdf>. Accessed October 24, 2022.

Sunlenca (lenacapavir sodium)

Prior Authorization Guideline

Guideline Name	Sunlenca (lenacapavir sodium)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Sunlenca (lenacapavir sodium)
Multidrug Resistant HIV-1 Infection Indicated in combination with other antiretroviral(s) for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

2 . Criteria

Product Name: Sunlenca	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - One of the following:	

1.1 All of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 Both of the following:

1.1.2.1 Patient is heavily treatment-experienced with multidrug resistance as confirmed by a resistance assay

AND

1.1.2.2 Patient is failing their current antiretroviral regimen due to one of the following:

- Resistance
- Intolerance
- Safety considerations

AND

1.1.3 Patient is currently taking, or will be prescribed, an active and optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

3 . References

1. Sunlenca Prescribing Information. Gilead Sciences, Inc. Foster City, CA. December 2022.

Prior Authorization Guideline

Guideline Name	Sunosi (solriamfetol)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Sunosi (solriamfetol)
Narcolepsy Indicated to improve wakefulness in adults patients with excessive daytime sleepiness associated with narcolepsy.
Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with obstructive sleep apnea (OSA). Limitations of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.

2 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]</p> <p style="text-align: center;">AND</p> <p>2 - BOTH of the following;</p> <p>2.1 Trial and failure, contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> • generic modafinil • generic armodafinil <p style="text-align: center;">AND</p> <p>2.2 ONE of the following:</p> <p>2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant</p> <p style="text-align: center;">OR</p> <p>2.2.2 History of or potential for a substance use disorder</p>	

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy.

Product Name: Sunosi

Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of obstructive sleep apnea defined by one of the following: [4]

1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

OR

1.2 Both of the following:

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]

AND

1.2.2 One of the following signs/symptoms are present:

- Daytime sleepiness
- Nonrestorative sleep
- Fatigue
- Insomnia
- Waking up with breath holding, gasping, or choking
- Habitual snoring noted by a bed partner or other observer
- Observed apnea

AND

2 - Both of the following:

2.1 Standard treatment(s) for the underlying obstruction (e.g., with continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

3 - Trial and failure, contraindication or intolerance to ONE of the following:

- generic modafinil
- generic armodafinil

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy.	
AND	
2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)	

3 . Endnotes

- A. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].
- B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].
- C. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [2].

4 . References

- 1. Sunosi Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. October 2021.
- 2. Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394.
- 3. UpToDate. Clinical features and diagnosis of narcolepsy. Available by subscription at: https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=Clinical%20features%20and%20diagnosis%20of%20narcolepsy&source=search_result&selectedTitle=1~116&usage_type=default&display_rank=1. Accessed March 30, 2020.
- 4. UpToDate. Clinical presentation and diagnosis of obstructive sleep apnea in adults. Available by subscription at: https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-obstructive-sleep-apnea-in-adults?search=obstructive%20sleep%20apnea&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4. Accessed March 30, 2020.

Prior Authorization Guideline

Guideline Name	Sutent (sunitinib) - PA, NF
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Sutent (sunitinib)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate.
Advanced pancreatic neuroendocrine tumors (pNET) Indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.
Advanced renal cell carcinoma Indicated for the treatment of advanced renal cell carcinoma.
Adjuvant treatment of renal cell carcinoma Indicated for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

2 . Criteria

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</p> <p style="text-align: center;">AND</p> <p>2 - History of disease progression, contraindication, or intolerance to Gleevec (imatinib)</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Brand Sutent	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)

Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of gastrointestinal stromal tumor (GIST)</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of disease progression, contraindication, or intolerance to Gleevec (imatinib)</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)</p> <p style="text-align: center;">AND</p>	

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Brand Sutent	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET)	

AND

2 - One of the following:

- unresectable locally advanced disease
- metastatic disease

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of advanced/metastatic renal cell carcinoma	
AND	
2 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)	
AND	

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib

Diagnosis	Advanced Renal Cell Carcinoma
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Brand Sutent

Diagnosis	Advanced Renal Cell Carcinoma
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of advanced/metastatic renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Brand Sutent, Generic sunitinib

Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of renal cell carcinoma (RCC)</p> <p style="text-align: center;">AND</p> <p>2 - Used as adjuvant therapy</p> <p style="text-align: center;">AND</p> <p>3 - Patient is at high risk of recurrent RCC following nephrectomy</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Brand Sutent	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of renal cell carcinoma (RCC)</p>	

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

AND

5 - Prescribed by or in consultation with an oncologist

3 . Endnotes

- A. The recommended dose of Sutent for the adjuvant treatment of RCC is 50mg taken orally once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off (Schedule 4/2), for nine 6-week cycles (approximately 1 year). [1, 2]

4 . References

1. Sutent Prescribing Information. Pfizer Labs. New York, NY. September 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Kidney Cancer. v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 15, 2021.

Sylatron (peginterferon alfa-2b)

Prior Authorization Guideline

Guideline Name	Sylatron (peginterferon alfa-2b)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Sylatron	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of melanoma with microscopic or gross nodal involvement</p> <p style="text-align: center;">AND</p> <p>2 - The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy</p>	

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Dermatologist

Product Name: Sylatron

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Sylatron therapy

2 . References

1. Sylatron Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. May 2018.

Prior Authorization Guideline

Guideline Name	Symdeko (tezacaftor/ivacaftor)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Symdeko (tezacaftor/ivacaftor)
Cystic Fibrosis (CF) Indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2 . Criteria

Product Name: Symdeko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is 6 years of age or older

AND

2 - Diagnosis of cystic fibrosis (CF) [2,3]

AND

3 - One of the following:

3.1 Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

3.2 Patient has at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based in vitro data and/or clinical evidence* as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Specialist affiliated with a CF care center

Notes

*Please consult Background section for table of CFTR gene mutations responsive to Symdeko.

Product Name: Symdeko

Approval Length

12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations) [2,3]</p>	

3 . Background

Clinical Practice Guidelines				
<p>CFTR Gene Mutations that are Responsive to Symdeko [1]</p> <p>*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves.</p> <p>[Last Reviewed: 1/11/21]</p>				
List of <i>CFTR</i> Gene Mutations that Produce <i>CFTR</i> Protein and are Responsive to Symdek				
<i>546insCTA</i>	<i>E92K</i>	<i>G576A</i>	<i>L346P</i>	<i>R117G</i>
<i>711+3A→G *</i>	<i>E116K</i>	<i>G576A;R668C</i> †	<i>L967S</i>	<i>R117H</i>
<i>2789+5G→A *</i>	<i>E193K</i>	<i>G622D</i>	<i>L997F</i>	<i>R117L</i>
<i>3272-26A→G *</i>	<i>E403D</i>	<i>G970D</i>	<i>L1324P</i>	<i>R117P</i>
<i>3849+10kbC→T *</i>	<i>E588V</i>	<i>G1069R</i>	<i>L1335P</i>	<i>R170H</i>
<i>A120T</i>	<i>E822K</i>	<i>G1244E</i>	<i>L1480P</i>	<i>R258G</i>
<i>A234D</i>	<i>E831X</i>	<i>G1249R</i>	<i>M152V</i>	<i>R334L</i>
<i>A349V</i>	<i>F191V</i>	<i>G1349D</i>	<i>M265R</i>	<i>R334Q</i>
<i>A455E *</i>	<i>F311del</i>	<i>H939R</i>	<i>M952I</i>	<i>R347H *</i>
<i>A554E</i>	<i>F311L</i>	<i>H1054D</i>	<i>M952T</i>	<i>R347L</i>
<i>A1006E</i>	<i>F508C</i>	<i>H1375P</i>	<i>P5L</i>	<i>R347P</i>

A1067T	F508C;S1251N †	I148T	P67L *	R352Q *
D110E	F508del ^	I175V	P205S	R352W
D110H *	F575Y	I336K	Q98R	R553Q
D192G	F1016S	I601F	Q237E	R668C
D443Y	F1052V	I618T	Q237H	R751L
D443Y;G576A;R668C †	F1074L	I807M	Q359R	R792G
D579G *	F1099L	I980K	Q1291R	R933G
D614G	G126D	I1027T	R31L	R1066H
D836Y	G178E	I1139V	R74Q	R1070Q
D924N	G178R	I1269N	R74W	R1070W *
D979V	G194R	I1366N	R74W;D1270N †	R1162L
D1152H *	G194V	K1060T	R74W;V201M †	R1283M
D1270N	G314E	L15P	R74W;V201M;D1270N †	R1283S
E56K	G551D	L206W *	R75Q	S549N
E60K	G551S	L320V	R117C *	S549R

* Clinical data for these mutations in Clinical Studies.

^ A patient must have two copies of the *F508del* mutation or at least one copy of a responsive mutation presented in Table 6 to be indicated.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations and these exist independent of the presence of mutations on the other allele.

4 . References

1. Symdeko Prescribing information. Vertex Pharmaceuticals Inc. Boston, MA. December 2020.
2. Cousar-Taylor J, Munch A, McKone E, et al. Tezacaftor-ivacaftor in patients with cystic fibrosis homozygous for phe508del. *N Engl J Med.* 2017; 1-11.
3. Rowe S, Daines C, Ringshausen F, et al. Tezacaftor-ivacaftor in residual-function heterozygotes with cystic fibrosis. *N Engl J Med.* 2017; 1-12.

Symlin (pramlintide acetate injection)

Prior Authorization Guideline

Guideline Name	Symlin (pramlintide acetate injection)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Symlin	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <ul style="list-style-type: none">• Type 1 diabetes• Type 2 diabetes <p style="text-align: center;">AND</p>	

2 - Patient has failed to achieve desired glucose control despite optimal insulin therapy

AND

3 - Patient is taking concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog)

Product Name: Symlin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline	
AND	
2 - Patient is receiving concurrent mealtime insulin therapy (e.g., Humulin, Humalog, Novolin, Novolog)	

2 . References

1. Symlin prescribing information. Amylin Pharmaceuticals, Inc. Wilmington, DE. April 2016

Prior Authorization Guideline

Guideline Name	Synagis (palivizumab)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Synagis (palivizumab)
<p>Prophylaxis of respiratory syncytial virus (RSV) Indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients: with a history of premature birth (less than or equal to 35 weeks gestational age) and who are 6 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with bronchopulmonary dysplasia (BPD) that required medical treatment within the previous 6 months and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season; with hemodynamically significant congenital heart disease (CHD) and who are 24 months of age or younger at the beginning of respiratory syncytial virus (RSV) season. Limitations of use: The safety and efficacy of Synagis have not been established for treatment of RSV disease.</p>

2 . Criteria

Product Name: Synagis	
Diagnosis	Premature Infants (without other indications)
Approval Length	5 month(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]</p> <p style="text-align: center;">AND</p> <p>2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].</p> <p style="text-align: center;">AND</p> <p>3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.</p> <p style="text-align: center;">AND</p> <p>4 - Not taken in combination with Beyfortus (nirsevimab) [4]</p>	
Notes	<p>Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A]</p> <p>Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (http://www.cdc.gov/surveillance/nrvss/rsv/index.html) to confirm the start of RSV season based on region.</p>

Product Name: Synagis	
Diagnosis	Chronic Lung Disease of Prematurity
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Chronic lung disease (CLD) of prematurity [2]

AND

2 - Born before 32 weeks, 0 days gestation [2]

AND

3 - Received greater than 21% oxygen supplementation for at least the first 28 days after birth

AND

4 - One of the following:

4.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

OR

4.2 Both of the following:

- Age at least 12 to < 24 months at the start of the RSV season
- Received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season

AND

5 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Neonatologist
- Pediatric intensivist
- Infectious disease specialist

AND

6 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region.

AND

7 - Not taken in combination with Beyfortus (nirsevimab)

Notes

Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A]

Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (<http://www.cdc.gov/surveillance/nrvss/rsv/index.html>) to confirm the start of RSV season based on region.

Product Name: Synagis

Diagnosis

Hemodynamically Significant Congenital Heart Disease

Approval Length

5 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Age < 12 months at the start of the respiratory syncytial virus (RSV) season, with one of the following: [C] (persons of all ages).

1.1.1 All of the following:

- Acyanotic heart failure
- Receiving medication to control congestive heart failure
- Patient will require a cardiac surgical procedure

OR

1.1.2 Moderate to severe pulmonary hypertension

OR

1.1.3 Cyanotic heart defect

OR

1.2 Both of the following*: [D]

- Age < 24 months
- Patient will or has undergone a cardiac transplantation during the respiratory syncytial virus (RSV) season

AND

2 - Prescribed by or in consultation with a pediatric cardiologist

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

4 - Not taken in combination with Beyfortus (nirsevimab)

Notes

Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. *ONE additional postoperative dose allowed for patients undergoing cardiac transplantation, cardiac bypass or extracorporeal membrane oxygenation. [A, D]

Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (<http://www.cdc.gov/surveillance/nrvss/rsv/index.html>) to confirm the start of RSV season based on region.

Product Name: Synagis	
Diagnosis	Pulmonary Abnormality or Neuromuscular Disorder
Approval Length	5 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]</p> <p style="text-align: center;">AND</p> <p>2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.</p> <p style="text-align: center;">AND</p> <p>3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Pediatric pulmonologist • Neurologist <p style="text-align: center;">AND</p> <p>5 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region</p> <p style="text-align: center;">AND</p>	

6 - Not taken in combination with Beyfortus (nirsevimab)

Notes

Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A]

Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (<http://www.cdc.gov/surveillance/nrvss/rsv/index.html>) to confirm the start of RSV season based on region.

Product Name: Synagis

Diagnosis Immunocompromised Children

Approval Length 5 month(s)

Guideline Type Prior Authorization

Approval Criteria

1 - Prescriber attests that patient is immunocompromised

AND

2 - Age < 24 months

AND

3 - Prescribed by or in consultation with one of the following:

- Pediatric pulmonologist
- Infectious disease specialist
- Pediatric intensivist

AND

4 - Used for the prevention of serious lower respiratory tract disease caused by respiratory

syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

5 - Not taken in combination with Beyfortus (nirsevimab)

Notes

Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A]

Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (<http://www.cdc.gov/surveillance/nrvss/rsv/index.html>) to confirm the start of RSV season based on region.

Product Name: Synagis

Diagnosis

Children with Cystic Fibrosis

Approval Length

5 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis [2]

AND

2 - One of the following:

2.1 Both of the following:

- Age < 12 months
- Clinical evidence of chronic lung disease (CLD) and/or nutritional compromise (i.e., failure to thrive)

OR

2.2 Both of the following:

- Age at least 12 to < 24 months
- Severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length < 10th percentile on pediatric growth chart [E]

AND

3 - Used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) during the respiratory syncytial virus (RSV) season for the patient's geographic region

AND

4 - Not taken in combination with Beyfortus (nirsevimab)

Notes

Authorization will be issued for up to a maximum of 5 months (5 doses) during respiratory syncytial virus (RSV) season. Initiation of Synagis prophylaxis after start of respiratory syncytial virus (RSV) season will not require all 5 doses for these conditions. [A]

Typical RSV season is from November through March; however, RSV season can fall outside this time frame. If outside this time frame, refer to the CDC surveillance reports (<http://www.cdc.gov/surveillance/nrvss/rsv/index.html>) to confirm the start of RSV season based on region.

3 . Endnotes

- A. Five monthly doses of palivizumab will provide more than 6 months of prophylactic serum palivizumab concentrations. Administration of more than five monthly doses is not recommended. If RSV season onset is in November, the first dose should be administered in November, and the fifth and final dose should be administered in March. If RSV season onset is in November and the first dose is given in January, the third and final dose should be administered in March. In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of palivizumab administration. [2] For analysis of National Respiratory and Enteric

Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report (MMWR), season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is at least 10% and RSV season offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is at least 10%. [3] NREVSS surveillance data can be viewed here (<http://www.cdc.gov/surveillance/nrevss/rsv/>)

- B. Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation. [2]
- C. The following conditions are NOT considered hemodynamically significant congenital heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonary stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus; lesions adequately corrected by surgery, unless continuing required medication for congestive heart failure; mild cardiomyopathy and not receiving medical therapy for the condition; children in the second year of life. [2]
- D. Pediatric growth charts can be viewed here (http://www.cdc.gov/growthcharts/who_charts.htm)
- E. Children undergoing these procedures should receive an additional dose of palivizumab as soon as possible after the procedure. Thereafter, doses should be administered monthly as scheduled. [2]
- F. Monthly prophylaxis should be discontinued in any infant or child who experiences a breakthrough RSV hospitalization. [2]
- G. Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease. [2]
- H. The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native populations and possibly in selected other American Indian populations. [2]

4 . References

1. Synagis Prescribing Information. Swedish Orphan Biovitrum AB (publ). Stockholm, Sweden September 2021.
2. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalizations for respiratory syncytial virus infection. *Pediatrics*. 2014 Aug;134(2):415-20. doi: 10.1542/peds.2014-1665.
3. Panozzo CA, Stockman LJ, et al. Use of respiratory syncytial virus surveillance data to optimize the timing of immunoprophylaxis. *Pediatrics*. 2010 Jul;126(1):e116-23.
4. Jones JM, Fleming-Dutra KE, Prill MM, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the Advisory Committee on Immunization Practices – United States, 2023. *MMWR Morb Mortal Wkly Rep*. 2023;72(34):920-925

Synribo (omacetaxine mepesuccinate)

Prior Authorization Guideline

Guideline Name	Synribo (omacetaxine mepesuccinate)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Synribo (omacetaxine mepesuccinate)
Chronic Myeloid Leukemia (CML) Indicated for the treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKIs).

2 . Criteria

Product Name: Synribo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic myelogenous leukemia	

AND

2 - Prescribed by or in consultation with a hematologist/oncologist [A]

Product Name: Synribo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Synribo should be prepared in a healthcare facility and administered by a healthcare professional. As omacetaxine mepesuccinate is an antineoplastic product, special handling and disposal procedures should be followed. [1]

4 . References

1. Synribo Prescribing Information. Cephalon, Inc. North Wales, PA. November 2020.

Tabrecta (capmatinib)

Prior Authorization Guideline

Guideline Name	Tabrecta (capmatinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Tabrecta (capmatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.

2 . Criteria

Product Name: Tabrecta	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of non-small cell lung cancer (NSCLC)

AND

2 - Disease is one of the following:

- Recurrent
- Advanced
- Metastatic

AND

3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Tabrecta

Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tabrecta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. May 2020.

Prior Authorization Guideline

Guideline Name	Tafinlar (dabrafenib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Tafinlar (dabrafenib)
<p>BRAF V600E mutation-positive unresectable or metastatic melanoma Indicated as a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma.</p> <p>BRAF V600E or V600K mutation-positive unresectable or metastatic melanoma Indicated in combination with trametinib for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma.</p> <p>BRAF V600E mutation-positive metastatic non-small cell lung cancer Indicated in combination with trametinib for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF NSCLC.</p> <p>BRAF V600E or V600K mutation-positive adjunctive treatment for melanoma Indicated for adjuvant treatment in combination with trametinib for patients with melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma</p> <p>Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated in combination with</p>

trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options. Limitation of use: Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.

BRAF V600E mutation-positive low-grade glioma Indicated, in combination with trametinib, for the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy.

2 . Criteria

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses: [2]</p> <ul style="list-style-type: none"> • Unresectable melanoma • Metastatic melanoma <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Cancer is BRAFV600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]</p>	

OR

2.2 Both of the following:

2.2.1 Cancer is BRAFV600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

2.2.2 Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic melanoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of metastatic non-small cell lung cancer	

AND

2 - Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

3 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Non-small cell lung cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Tafinlar	
Diagnosis	Adjunctive treatment for melanoma
Approval Length	12 Month [A]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of melanoma	
AND	

2 - Cancer is BRAF V600E mutation or V600K mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Involvement of lymph nodes following complete resection [2]

AND

4 - Used as adjunctive therapy

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar

Diagnosis	Anaplastic thyroid cancer (ATC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of locally advanced or metastatic anaplastic thyroid cancer (ATC) [2]

AND

2 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Cancer may not be treated with standard locoregional treatment options

AND

4 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar

Diagnosis	Anaplastic thyroid cancer (ATC)
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

Product Name: Tafinlar

Diagnosis	Unresectable or metastatic solid tumors
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 6 years of age or older

AND

3 - Disease is one of the following:

- unresectable
- metastatic

AND

4 - Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options

AND

5 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

6 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar	
Diagnosis	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Tafenlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of low-grade glioma</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient requires systemic therapy</p> <p style="text-align: center;">AND</p> <p>4 - Cancer is BRAF V600E mutation type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p> <p style="text-align: center;">AND</p> <p>5 - Medication is used in combination with Mekinist (trametinib)</p>	

Product Name: Tafenlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. The recommended dosage of TAFINLAR is 150 mg orally taken twice daily in combination with trametinib until disease recurrence or unacceptable toxicity for up to 1 year for the adjuvant treatment of melanoma [1].

4 . References

1. Tafinlar Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. May 2023.
2. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 14, 2023.

Prior Authorization Guideline

Guideline Name	Tagrisso (osimertinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Tagrisso (osimertinib)
First-line Treatment of EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
Previously Treated EGFR T790M Mutation-Positive Metastatic NSCLC Indicated for the treatment of patients with metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test, whose disease has progressed on or after EGFR tyrosine kinase inhibitor (TKI) therapy.
Adjuvant Treatment of EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC) Indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

2 . Criteria

Product Name: Tagrisso

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following

1.1 All of the following:

1.1.1 Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

1.1.2 One of the following:

1.1.2.1 Both of the following:

1.1.2.1.1 Patient has a known active epidermal growth factor receptor (EGFR) T790M mutation as detected by a U.S. Food and Drug Administration (FDA) -approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.2.1.2 Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): [1-3]

- Gilotrif (afatinib)*
- Iressa (gefitinib)*
- Tarceva (erlotinib)*
- Vizimpro (dacomitinib)*

OR

1.1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.1.3 Prescribed by or in consultation with an oncologist

OR

1.2 All of the following:

1.2.1 Diagnosis of non-small cell lung cancer (NSCLC)

AND

1.2.2 Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

1.2.3 Both of the following:

- Patient is receiving as adjuvant therapy
- Patient has had a complete surgical resection of the primary non-small cell lung cancer (NSCLC) tumor

AND

1.2.4 Prescribed by or in consultation with an oncologist

Notes	*This product may require prior authorization.
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Product Name: Tagrisso	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

- 1 - Documentation of continued clinical benefit with therapy [A]

3 . Endnotes

- A. Tagrisso (osimertinib) may be continued as a single agent therapy in patients with NSCLC and known sensitizing EGFR mutation following disease progression (Category 2A). [2, 3]

4 . References

1. Tagrisso prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. December 2020.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2014. Updated periodically. Available by subscription at: www.nccn.org. Accessed March 13, 2020.
3. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 13, 2020.

Taltz (ixekizumab)

Prior Authorization Guideline

Guideline Name	Taltz (ixekizumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Taltz (ixekizumab)
Plaque Psoriasis (PsO) Indicated for the treatment of patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis.
Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis.
Non-radiographic Axial Spondyloarthritis (nr-axSpA) Indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation.

2 . Criteria

Product Name: Taltz

Diagnosis	Plaque Psoriasis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe plaque psoriasis

AND

2 - One of the following [2]:

- Greater than or equal to 3% body surface area involvement
- Severe scalp psoriasis
- Palmoplantar (i.e., palms, soles), facial, or genital involvement

AND

3 - Patient is 6 years of age or older

AND

4 - Minimum duration of a 4-week trial and failure, contraindication, or intolerance to one of the following topical therapies [3]:

- corticosteroids (e.g., betamethasone, clobetasol)
- vitamin D analogs (e.g., calcitriol, calcipotriene)
- tazarotene
- calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- anthralin
- coal tar

AND

5 - Prescribed by or in consultation with a dermatologist

AND

6 - One of the following:

6.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Skyrizi (risankizumab)
- Stelara (ustekinumab)
- Tremfya (guselkumab)

OR

6.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:	
<ul style="list-style-type: none">• Reduction the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active psoriatic arthritis</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [4]:</p> <ul style="list-style-type: none"> • Actively inflamed joints • Dactylitis • Enthesitis • Axial disease • Active skin and/or nail involvement <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Dermatologist • Rheumatologist <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> • Cimzia (certolizumab pegol) • Enbrel (etanercept) • Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm • Simponi (golimumab) • Stelara (ustekinumab) • Tremfya (guselkumab) • Skyrizi (risankizumab-rzaa) • Rinvoq (upadacitinib) • Xeljanz/XR (tofacitinib/ER) 	

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 4]: <ul style="list-style-type: none">• Reduction in the total active (swollen and tender) joint count from baseline• Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline• Reduction in the body surface area (BSA) involvement from baseline	

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of active ankylosing spondylitis <p style="text-align: center;">AND</p> 2 - Prescribed by or in consultation with a rheumatologist	

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE of the following, or attestation demonstrating a trial may be inappropriate*:

- Cimzia (certolizumab pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

4.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Notes	* Includes attestation that a total of two TNF inhibitors have already been tried in the past, and the patient should not be made to try a third TNF inhibitor.
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Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 5]:

- Disease activity (e.g., pain, fatigue, inflammation, stiffness)
- Lab values (erythrocyte sedimentation rate, C-reactive protein level)
- Function
- Axial status (e.g., lumbar spine motion, chest expansion)
- Total active (swollen and tender) joint count

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of active non-radiographic axial spondyloarthritis</p> <p style="text-align: center;">AND</p> <p>2 - Patient has objective signs of inflammation (e.g., C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) [1, 3]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a rheumatologist</p> <p style="text-align: center;">AND</p> <p>4 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [5]</p>	

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to Cimzia (certolizumab pegol)

OR

5.2 For continuation of prior Taltz therapy, defined as no more than a 45-day gap in therapy

Product Name: Taltz	
Diagnosis	Non-radiographic Axial Spondyloarthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 5]:	
<ul style="list-style-type: none">• Disease activity (e.g., pain, fatigue, inflammation, stiffness)• Lab values (erythrocyte sedimentation rate, C-reactive protein level)• Function• Axial status (e.g., lumbar spine motion, chest expansion)• Total active (swollen and tender) joint count	

3 . References

1. Taltz prescribing information. Eli Lilly and Company. Indianapolis, IN. May 2022.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
5. Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.

Prior Authorization Guideline

Guideline Name	Talzenna (talazoparib) - PA, NF
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Talzenna (talazoparib)
<p>Breast Cancer Indicated for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA.</p> <p>HRR Gene-mutated mCRPC Indicated in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).</p>

2 . Criteria

Product Name: Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Trial and failure, contraindication, or intolerance to Lynparza</p> <p style="text-align: center;">OR</p> <p> 2.2 For continuation of prior therapy</p>	

Product Name: Talzenna	
Diagnosis	Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic castration-resistant prostate cancer (mCRPC)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is homologous recombination repair (HRR) gene-mutated</p> <p style="text-align: center;">AND</p> <p>3 - Taken in combination with Xtandi (enzalutamide)</p>	

Product Name: Talzenna	
Diagnosis	Breast Cancer, Prostate Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Talzenna	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Paid claims or submission of medical records (e.g., chart notes) confirming a trial and failure, contraindication, or intolerance to Lynparza</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 45-day gap in therapy</p>	

3 . References

1. Talzenna Prescribing Information. Pfizer Labs. New York, NY. June 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v8.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 28, 2021.

Tarceva (erlotinib)

Prior Authorization Guideline

Guideline Name	Tarceva (erlotinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Tarceva	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of locally advanced or metastatic (stage III or IV) non-small cell lung cancer (NSCLC) [2] AND 2 - Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions,	

exon 21 (L858R) substitution, exon 18 (G719X, G719) or exon 20 (S7681) mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility [2]

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Tarceva	
Diagnosis	Non-Small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Tarceva therapy	

Product Name: Tarceva	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following diagnoses:	
<ul style="list-style-type: none">• Locally advanced pancreatic cancer• Unresectable pancreatic cancer• Metastatic pancreatic cancer	
AND	

2 - Used in combination with Gemzar (gemcitabine)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Tarceva	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Tarceva therapy	

2 . References

1. Tarceva Prescribing Information. Genentech USA, Inc. South San Francisco, CA. October 2016.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. v.1.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed October 23, 2018.

Targretin (bexarotene)

Prior Authorization Guideline

Guideline Name	Targretin (bexarotene)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Targretin (bexarotene) capsules
Cutaneous T-Cell Lymphoma Indicated for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.
Drug Name: Targretin (bexarotene) gel 1%
Cutaneous T-Cell Lymphoma Indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma (Stage 1A and 1B) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

2 . Criteria

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cutaneous T-cell lymphoma (CTCL) [A]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [e.g., corticosteroids {i.e., clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}, topical mechlorethamine, phototherapy, etc] or systemic therapies [e.g., brentuximab vedotin, methotrexate, etc])</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to generic Targretin (Applies to brand Targretin only)</p>	

Product Name: Brand Targretin capsules, Generic bexarotene capsules, Brand Targretin gel, Generic bexarotene Gel	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of disease progression while on therapy</p>	

3 . Endnotes

- A. Cutaneous T-cell lymphomas (CTCLs) are a group of non-Hodgkin's lymphomas (NHLs) primarily developing in the skin and at times progress to involve lymph nodes, blood, and visceral organs. Mycosis fungoides (MF) is the most common subtype and is usually associated with an indolent clinical course with intermittent, stable, or slow progression of the lesions. Extracutaneous involvement (lymph nodes, blood, or less commonly,

other organs) or large cell transformation (LCT) may be seen in advanced-stage disease. Sezary Syndrome (SS) is a rare erythrodermic, leukemic variant of CTCL and is characterized by significant blood involvement, erythroderma, and often lymphadenopathy. Primary cutaneous CD30+ T cell lymphoproliferative disorders are also included as a subtype of CTCL. [3]

4 . References

1. Targretin prescribing information. Bausch Health US, LLC. Bridgewater, NJ. April 2020.
2. Targretin gel 1% prescribing information. Bausch Health US, LLC. Bridgewater, NJ. February 2020.
3. National Comprehensive Cancer Network (NCCN). Primary Cutaneous Lymphomas v.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed on July 26, 2023.

Prior Authorization Guideline

Guideline Name	Tarpeyo (budesonide) - PA, NF
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Tarpeyo (budesonide)
Primary Immunoglobulin A Nephropathy (IgAN) Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

2 . Criteria

Product Name: Tarpeyo	
Approval Length	9 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m²

AND

5 - ONE of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: [2]

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

Product Name: Tarpeyo

Approval Length | 9 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of primary immunoglobulin A nephropathy (IgAN) as confirmed by a kidney biopsy [A]

AND

2 - Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool] [B]

AND

3 - Used to reduce proteinuria

AND

4 - Submission of medical records (e.g., chart notes) confirming estimated glomerular filtration rate (eGFR) greater than or equal to 35 mL/min/1.73 m²

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:

5.1 Patient has been on a minimum 90-day trial of a maximally tolerated dose and will continue to receive therapy with one of the following: [2]

- An angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril)
- An angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan)

OR

5.2 Patient has a contraindication or intolerance to both ACE inhibitors and ARBs

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to another glucocorticoid (e.g., methylprednisolone, prednisone)

AND

7 - Prescribed by or in consultation with a nephrologist

3 . Endnotes

- A. IgAN can only be diagnosed with a kidney biopsy. [2]
- B. The International IgAN Prediction Tool incorporates clinical information at the time of biopsy and is a valuable resource to quantify risk of progression and inform shared decision-making with patients. [2]

4 . References

1. Tarpeyo Prescribing Information. Calliditas Therapeutics AB. Stockholm, Sweden. December 2021.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021;100(4S):S1-S276.

Prior Authorization Guideline

Guideline Name	Tasigna (nilotinib)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Tasigna (nilotinib)
Newly diagnosed Ph+ Chronic Myeloid Leukemia Indicated for the treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP) Indicated for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant to or intolerant to prior therapy that included imatinib.
Resistant or intolerant CML in chronic phase (CP) and accelerated phase (AP), Pediatric Indicated for pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.

2 . Criteria

Product Name: Tasigna	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) chronic myelogenous/myeloid leukemia (CML) (A)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • oncologist • hematologist <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to generic imatinib</p> <p style="text-align: center;">OR</p> <p>4.2 Continuation of prior therapy</p>	

Product Name: Tasigna	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . Endnotes

- A. BCR-ABL1 refers to a gene sequence found in an abnormal chromosome 22. The cause of chronic myelogenous leukemia (CML) can be traced to a single, specific genetic abnormality in one chromosome. The presence of the gene sequence known as BCR-ABL1 confirms the diagnosis of CML.

4 . References

1. Tasigna Prescribing Information. Novartis Pharmaceutical Corporation. East Hanover, NJ. September 2021.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic Myelogenous Leukemia v.1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf. Accessed March 27, 2023.

Tavalisse (fostamatinib)

Prior Authorization Guideline

Guideline Name	Tavalisse (fostamatinib)
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Guideline Note:

Effective Date:	7/1/2023
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1 . Indications

Drug Name: Tavalisse (fostamatinib)
Chronic Idiopathic Thrombocytopenic Purpura (ITP) Indicated for the treatment of thrombocytopenia in adult patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.

2 . Criteria

Product Name: Tavalisse	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of one of the following:	

- Chronic immune (idiopathic) thrombocytopenic purpura (ITP) [1]
- Relapsed/refractory ITP [3]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following: [1-4]

- Corticosteroids (e.g., dexamethasone, prednisone)
- Immune globulins (e.g., Gammalex, Gammagard S/D)
- Splenectomy

AND

4 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding [3]

AND

5 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Tavalisse	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding	

3 . References

1. Tavalisse Prescribing Information. Rigel Pharmaceuticals, Inc. South San Francisco, CA. November 2020.
2. Neunert C, Terrell D, Arnold D, et al. The American Society of Hematology 2019 Evidence-based practice guideline for immune thrombocytopenia. Available at: <https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for>. Accessed December 8, 2022.
3. Per clinical consult with hematologist/oncologist. June 20, 2018.
4. Bussel J, Arnold DM, Grossbard E, et al. Fostamatinib for the treatment of adult persistent and chronic immune thrombocytopenia: Results of two phase 3, randomized, placebo-controlled trials. *Am J Hematol.* 2018;93:921-30.

Prior Authorization Guideline

Guideline Name	Tavneos (avacopan) - PA, NF
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Guideline Note:

Effective Date:	10/1/2022
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1 . Indications

Drug Name: Tavneos (avacopan)
Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis Indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

2 . Criteria

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:

- Granulomatosis with polyangiitis (GPA)
- Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

- ANCA test positive for proteinase 3 (PR3) antigen
- ANCA test positive for myeloperoxidase (MPO) antigen
- Tissue biopsy

AND

3 - Patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

- cyclophosphamide
- rituximab

AND

4 - One of the following:

4.1 Patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 History of contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist

- Rheumatologist

Product Name: Tavneos	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p> <p style="text-align: center;">AND</p> <p>2 - Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab)</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Nephrologist • Pulmonologist • Rheumatologist 	

Product Name: Tavneos	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:</p>	

- Granulomatosis with polyangiitis (GPA)
- Microscopic polyangiitis (MPA)

AND

2 - Diagnosis is confirmed by one of the following: [4]

- ANCA test positive for proteinase 3 (PR3) antigen
- ANCA test positive for myeloperoxidase (MPO) antigen
- Tissue biopsy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming patient is receiving concurrent immunosuppressant therapy with one of the following: [1-3]

- cyclophosphamide
- rituximab

AND

4 - One of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient is concurrently on glucocorticoids (e.g., prednisone)

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming contraindication or intolerance to glucocorticoids (e.g., prednisone)

AND

5 - Prescribed by or in consultation with one of the following:

- Nephrologist
- Pulmonologist

- Rheumatologist

3 . References

1. Tavneos Prescribing Information. ChemoCentryx, Inc. San Carlos, CA. October 2021.
2. Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. *N Engl J Med.* 2021;384(7):599-609. doi:10.1056/NEJMoa2023386
3. Per clinical consult with rheumatologist November 17, 2021.
4. Falk RJ, Merkel PA, King TE. Granulomatosis with polyangiitis and microscopic polyangiitis: clinical manifestations and diagnosis. In: Post T, ed. UpToDate. UpToDate; 2021. Accessed December 8, 2021. www.uptodate.com.

Prior Authorization Guideline

Guideline Name	Tazverik (tazemetostat) - PA, NF
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Tazverik (tazemetostat)
<p>Epithelioid Sarcoma Indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).</p> <p>Follicular Lymphoma Indicated for the treatment of adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies. Also indicated for the treatment of adult patients with R/R FL who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).</p>

2 . Criteria

Product Name: Tazverik

Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of epithelioid sarcoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Metastatic • Locally advanced <p style="text-align: center;">AND</p> <p>3 - Patient is not eligible for complete resection</p>	

Product Name: Tazverik	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of follicular lymphoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p>	

- Relapsed
- Refractory

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma, Follicular Lymphoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of disease progression while on therapy</p>	

Product Name: Tazverik	
Diagnosis	Epithelioid Sarcoma
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of epithelioid sarcoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Metastatic • Locally advanced <p style="text-align: center;">AND</p> <p>3 - Patient is not eligible for complete resection</p>	

Product Name: Tazverik	
Diagnosis	Follicular Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of follicular lymphoma</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Relapsed • Refractory 	

3 . References

1. Tazverik prescribing information. Epizyme, Inc. Cambridge, MA. July 2020.

Technivie (ombitasvir, paritaprevir and ritonavir)

Prior Authorization Guideline

Guideline Name	Technivie (ombitasvir, paritaprevir and ritonavir)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Technivie	
Diagnosis	Chronic Hepatitis C - Genotype 4
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C genotype 4 AND 2 - One of the following:	

2.1 Patient is without cirrhosis

OR

2.2 Patient has compensated cirrhosis

AND

3 - Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Patient is not receiving Technivie in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Olysio (simeprevir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh B or C)

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to **ONE** of the following:

- Epclusa (sofosbuvir/velpatasvir)
- Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Technivie therapy

2 . References

1. Technivie Prescribing Information. AbbVie, Inc. North Chicago, IL. November 2017.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2017. <http://www.hcvguidelines.org/full-report-view>. Accessed January 2, 2018.

Tegsedi (inotersen)

Prior Authorization Guideline

Guideline Name	Tegsedi (inotersen)
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Guideline Note:

Effective Date:	10/1/2023
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1 . Indications

Drug Name: Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) with polyneuropathy	

AND

2 - Patient has a transthyretin (TTR) mutation (e.g., V30M) [1-4]

AND

3 - Prescribed by or in consultation with a neurologist

AND

4 - One of the following [2, 4]:

- Patient has a baseline polyneuropathy disability (PND) score \leq IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 10 and 130

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

Product Name: Tegsedi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient has demonstrated a benefit from therapy (e.g., improved neurologic impairment, slowing of disease progression, quality of life assessment)	
AND	

2 - One of the following [2, 4]:

- Patient continues to have a polyneuropathy disability (PND) score \leq IIIb
- Patient continues to have a familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient continues to have a neuropathy impairment score (NIS) between 10 and 130

3 . References

1. Onpattro Prescribing Information. Alnylam Pharmaceuticals, Inc. Cambridge, MA. January 2023.
2. Adams D, Suhr OB, Dyck PJ, et al. Trial design and rationale for APOLLO, a phase 3, placebo-controlled study of patisiran in patients with hereditary ATTR amyloidosis with polyneuropathy. *BMC Neurol.* 2017;17:181.
3. Tegsedi Prescribing Information. Akcea Therapeutics, Inc. Boston, MA. June 2022.
4. Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. *N Engl J Med.* 2018;379(1):22-31.

Temodar (temozolomide)

Prior Authorization Guideline

Guideline Name	Temodar (temozolomide)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Temodar (temozolomide)
Newly Diagnosed Glioblastoma Indicated for the treatment of adult patients with newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment.
Refractory Anaplastic Astrocytoma Indicated for the treatment of adult patients with refractory anaplastic astrocytoma, who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

2 . Criteria

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Glioblastoma, Anaplastic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Glioblastoma
- Anaplastic Astrocytoma

AND

2 - Both of the following (applies to BRAND Temodar only):

2.1 Trial and failure or intolerance to generic temozolamide

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Temodar, generic temozolomide	
Diagnosis	Glioblastoma, Anaplastic Astrocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

AND

2 - Both of the following (applies to BRAND Temodar only):

2.1 Trial and failure or intolerance to generic temozolamide

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

- Allergic response or intolerance to one of the inactive ingredients of the generic drug
- Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . References

1. Temodar Prescribing Information, Merck & Co, Inc. Whitehouse Station, NJ. November 2019.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Central Nervous System Cancers v.2.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed on July 6, 2022.

Prior Authorization Guideline

Guideline Name	Tepmetko (tepotinib) - PA, NF
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Tepmetko (tepotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

2 . Criteria

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer (NSCLC)	

AND
2 - Disease is metastatic
AND
3 - Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]
AND
4 - Prescribed by or in consultation with an oncologist
AND
5 - Trial and failure, contraindication, or intolerance to Tabrecta

Product Name: Tepmetko	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

Product Name: Tepmetko	
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of non-small cell lung cancer (NSCLC)

AND

1.1.2 Disease is metastatic

AND

1.1.3 Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations [A]

AND

1.1.4 Prescribed by or in consultation with an oncologist

AND

1.1.5 Trial and failure, contraindication, or intolerance to Tabrecta

OR

1.2 For continuation of prior therapy

3 . Endnotes

- A. An FDA-approved test for detection of MET exon 14 skipping alterations in NSCLC for selecting patients for treatment with Tepmetko is not available. Testing for the presence of MET exon 14 skipping alterations in plasma specimens is recommended only in patients for whom a tumor biopsy cannot be obtained. [1]

4 . References

1. Tepmetko Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2021.
2. Paik PK, Felip E, Veillon R, et al. Tepotinib in non-small-cell lung cancer with MET exon 14 skipping mutations. *N Engl J Med.* 2020;383(10):931-943.
doi:10.1056/NEJMoa2004407
3. Per clinical consult with oncologist, March 11, 2021.

Prior Authorization Guideline

Guideline Name	Teriparatide Products - PA, NF
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Forteo (teriparatide injection), Teriparatide (teriparatide injection)
<p>Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, teriparatide reduces the risk of vertebral and nonvertebral fractures.</p> <p>Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture Indicated to increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.</p> <p>Men and women with glucocorticoid-induced osteoporosis at high risk for fracture Indicated for the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.</p>

2 . Criteria

Product Name: Forteo	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of postmenopausal osteoporosis or osteopenia</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [2,4,8,10,D]</p> <p> 2.1 For diagnosis of osteoporosis, both of the following:</p> <p> 2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">AND</p> <p> 2.1.2 One of the following:</p> <p> 2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm</p> <p style="text-align: center;">OR</p> <p> 2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])</p> <p style="text-align: center;">OR</p> <p> 2.2 For diagnosis of osteopenia, both of the following:</p>	

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial and failure or intolerance to both of the following:

- Brand Teriparatide
- Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of postmenopausal osteoporosis or osteopenia</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [2,4,8,10,D]</p> <p>2.1 For diagnosis of osteoporosis, both of the following:</p> <p>2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">AND</p> <p>2.1.2 One of the following:</p> <p>2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm</p>	

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - One of the following: [7,B]

3.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo, Brand Teriparatide	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following: [7,B]	
1.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime	
OR	
1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])	

Product Name: Forteo	
Diagnosis	Postmenopausal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Brand Teriparatide
- Tymlos (abaloparatide)

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo	
Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of primary or hypogonadal osteoporosis or osteopenia</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [2,4,8,10,D]</p> <p> 2.1 For diagnosis of osteoporosis, both of the following:</p> <p> 2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">AND</p> <p> 2.1.2 One of the following:</p> <p> 2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm</p> <p style="text-align: center;">OR</p> <p> 2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])</p>	

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Trial and failure or intolerance to Brand Teriparatide

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Teriparatide

Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
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Approval Length	24 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - One of the following: [7,B]

3.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

3.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo, Brand Teriparatide

Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo

Diagnosis	Primary or hypogonadal osteoporosis or osteopenia at high risk for fracture
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Approval Length	24 month(s)
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Guideline Type

Non Formulary

Approval Criteria

1 - Diagnosis of primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,8,10,D]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [F]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Brand Teriparatide

AND

4 - One of the following: [7,B]

4.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

4.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of glucocorticoid-induced osteoporosis</p> <p style="text-align: center;">AND</p> <p>2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following: [8,A]</p> <p style="padding-left: 20px;">3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">OR</p> <p>3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:</p> <ul style="list-style-type: none">• Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions• Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions	

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following:

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - Trial and failure or intolerance to Brand Teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Brand Teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of glucocorticoid-induced osteoporosis</p> <p style="text-align: center;">AND</p> <p>2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following: [8,A]</p> <p style="padding-left: 20px;">3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p> <p style="text-align: center;">OR</p> <p>3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:</p> <ul style="list-style-type: none"> • Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions • Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions <p style="text-align: center;">OR</p> <p>3.3 History of one of the following fractures resulting from minimal trauma:</p>	

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - One of the following: [7,B]

5.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

5.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo, Brand Teriparatide	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following: [7,B]

1.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

1.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

Product Name: Forteo	
Diagnosis	Glucocorticoid-induced osteoporosis at high risk for fracture
Approval Length	24 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of glucocorticoid-induced osteoporosis</p> <p>AND</p> <p>2 - History of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months [C]</p> <p>AND</p> <p>3 - One of the following: [8,A]</p> <p>3.1 BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site)</p>	

OR

3.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities:

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

OR

3.3 History of one of the following fractures resulting from minimal trauma:

- Vertebral compression fracture
- Fracture of the hip
- Fracture of the distal radius
- Fracture of the pelvis
- Fracture of the proximal humerus

OR

3.4 One of the following:

- Glucocorticoid dosing of at least 30 mg per day
- Cumulative glucocorticoid dosing of at least 5 grams per year

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one bisphosphonate (e.g., alendronate) [E]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Brand Teriparatide

AND

6 - One of the following: [7,B]

6.1 Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime

OR

6.2 Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide])

3 . Definitions

Definition	Description
Dual x-ray absorptiometry (DXA) [3]	A diagnostic test used to assess bone density in the spine, hip, or wrist using radiation exposure about one tenth that of a standard chest x-ray. Central DXA (spine, hip) is the preferred measurement for definitive diagnosis and for monitoring the effects of therapy.
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
Quantitative computed tomography (QCT) [3]	A diagnostic test used to assess bone density; reflects three-dimensional bone mineral density. Usually used to assess the lumbar spine, but has been adapted for other skeletal sites. It is also possible to measure trabecular and cortical bone density in the periphery by peripheral QCT (pQCT).
T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.

Z-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for persons of the same age and sex.
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4 . Endnotes

- A. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoporosis, patients considered at high risk of fractures are as follows: (a) prior osteoporotic fracture, (b) a hip or spine BMD T-score less than or equal to -2.5, (c) FRAX 10-year risk of hip or major osteoporotic fracture at 3 percent or more and 20 percent or more, respectively, or (d) glucocorticoid use of at least 30mg per day or cumulative glucocorticoid doses of at least 5 grams per year. [9]
- B. Use for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture. [1]
- C. Most of the evidence supporting the efficacy of Forteo is based on studies evaluating its use in the treatment of glucocorticoid-induced osteoporosis (GIOP). To identify high risk patients, the GIOP studies (Saag et al, 2009) included patients with a history of prednisone or its equivalent at a dose greater than or equal to 5 mg/day for greater than or equal to 3 months. [5, 6]
- D. According to AACE, alendronate, risedronate, zoledronic acid, or denosumab have evidence for broad spectrum anti-fracture efficacy (spine, hip, nonvertebral fracture risk reduction) and are appropriate as initial therapy for most patients at high risk of fracture. Raloxifene or ibandronate may be appropriate initial therapy in some cases where patients requiring drugs with spine-specific efficacy. Teriparatide has been shown to reduce the risk of vertebral and nonvertebral fractures. It is recommended for patients with very high fracture risk or those in whom bisphosphonate therapy has been ineffective. [2]
- E. According to ACR, oral bisphosphonates are considered first-line for patients with glucocorticoid-induced osteoporosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. If bisphosphonate therapy is not appropriate, teriparatide should be considered. [9]
- F. The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

5 . References

1. Forteo prescribing information. Eli Lilly and Company. Indianapolis, IN. April 2021.
2. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: <https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice>. Accessed May 6, 2021.
3. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): National Osteoporosis Foundation; 2013.

4. North American Menopause Society. Management of postmenopausal osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. *Menopause* 2010;17(1):25-54.
5. Per clinical consult with bone disease specialist, September 26, 2011.
6. Saag KG, Zanchetta JR, Devogelaer JP, et al. Effects of teriparatide versus alendronate for treating glucocorticoid-induced osteoporosis: thirty-six-month results of a randomized, double-blind, controlled trial. *Arthritis Rheum.* 2009;60(11):3346-55.
7. Tymlos prescribing information. Radius Health, Inc. Waltham, MA. April 2021.
8. Per clinical consultation with endocrinologists. January 23 & 30, 2018.
9. American College of Rheumatology guideline for the prevention and treatment of glucocorticoid-induced osteoporosis: 2022 edition. Available at: <https://rheumatology.org/glucocorticoid-induced-osteoporosis-guideline>. Accessed May 2023.
10. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. *J Clin Endocrin Metab.* 2019; 104(5):1595-1622.
11. Teriparatide prescribing information. Alvogen, Inc. Morristown, NJ. November 2019.

Prior Authorization Guideline

Guideline Name	Testosterone Products
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males < 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Secondary hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Secondary hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum levels but have gonadotropins in the normal or low range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males < 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone)

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with

"age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)-idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in adult males with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in adult males with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, Depo-Testosterone, Fortesta, Methitest, Natesto, Testim, Testopel, Vogelxo, Xyosted

Off Label Uses: Transgender male (female-to-male) - Gender Dysphoria/Gender Incongruence [12-13, 18] Testosterone in 3 different formulations, including transdermal gel, significantly increased testosterone levels from the physiological range for women to the normal male range by week 30 of treatment in an observational study in female-to-male transsexual individuals. Hormonal sex reassignment therapy was associated with significantly fewer symptoms related to social distress, anxiety, and depression compared with those not receiving hormonal therapy in 1 cross-sectional study. Gender transition treatment can be initiated in adults and adolescents with confirmed persistent gender dysphoria/gender incongruence who have the capacity to make fully informed decisions and consent, usually by age 16 years, and have well-controlled, if any, mental health concerns. The goals of therapy

are to suppress endogenous sex hormones of the designated gender and to replace these with endogenous sex hormones of the affirmed gender. Either parenteral or transdermal testosterone may be used to achieve and maintain testosterone levels in the normal male range. Avoid sustained supraphysiologic levels to reduce risk of adverse reactions. Compelling reasons may exist to initiate therapy at younger than 16 years; although, studies in this population are minimal. Initial therapy to undergo suppression of pubertal development at Tanner stages G2/B2 is suggested. Neither puberty suppression nor gender-affirming hormone therapies are recommended in pre-pubertal children.

Drug Name: Jatenzo (testosterone undecanoate capsule, liquid filled)

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

2 . Criteria

Product Name: Androderm, Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Natesto, Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Testopel, Xyosted

Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab** [8-9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (less than 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Brand Depo-Testosterone, Brand Testosterone Cypionate, and Brand Testosterone Propionate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

7 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Axiron, and Brand Natesto only)

Notes

**This may require treatment to be temporarily held.

Product Name: Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab** [8-9]</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">4.2 Both of the following:</p> <p style="padding-left: 40px;">4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)</p> <p style="text-align: center;">AND</p>	

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (less than 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes

**This may require treatment to be temporarily held.

Product Name: Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando

Diagnosis

Male hypogonadism

Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)

AND

2 - Male patient at birth [C]

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab*** [8-9]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (less than 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to all of the following:

- Androderm (testosterone patch)

<ul style="list-style-type: none"> Generic testosterone gel 	
Notes	**These products may require prior authorization. ***This may require treatment to be temporarily held.

Product Name: Brand Fortesta, Brand Testim, Brand Vogelxo gel and pump	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (less than 10.4 nmol/L) or less than the reference range for the lab*** [8-9]</p> <p style="text-align: center;">OR</p> <p>4.2 Both of the following:</p>	

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (less than 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to all of the following:

- Androderm (testosterone patch)
- Generic testosterone gel

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Fortesta, Testosterone gel 10 mg/act (2)%, Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Testopel, Tlando, Xyosted

Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26, D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Brand Depo-Testosterone, Brand Testosterone Cypionate):

- Generic testosterone cypionate

- Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

5 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name: Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26, D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]</p> <p>AND</p> <p>2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]</p>	

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Fortesta, Testosterone gel 10 mg/act (2%), Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Generic testosterone cypionate, Testopel, Tlando, Xyosted

Diagnosis	Male hypogonadism, Gender dysphoria/Gender Incongruence
Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6

months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

2 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

Product Name: Methitest, Generic testosterone enanthate, Testopel, Generic methyltestosterone [off-label]

Diagnosis	Delayed puberty [E]
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Approval Length	6 month(s)
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel)

- Generic testosterone cypionate [F]
- Generic testosterone enanthate

Product Name: Generic testosterone cypionate [off-label]

Diagnosis	Delayed puberty [E]
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Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of delayed puberty [A]</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p>	

Product Name: Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Breast cancer is inoperable</p> <p style="text-align: center;">AND</p> <p>3 - Used for palliative treatment</p> <p style="text-align: center;">AND</p> <p>4 - Female patient at birth [C]</p>	

AND

5 - Trial and failure or intolerance to both of the following (applies to Brand Testosterone Enanthate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

3 . Endnotes

- A. Delayed puberty is defined as the lack of the initial signs of sexual maturation by an age that is more than 2-2.5 standard deviations above the mean for the population (traditionally, the age of 14 years in boys and 13 years in girls). In most cases, delayed puberty is not due to an underlying pathology, but instead represents an extreme end of the normal spectrum of pubertal timing, a developmental pattern referred to as constitutional delay of growth and puberty (CDGP). CDGP is the most common cause of delayed puberty in both sexes, but it can be diagnosed only after underlying conditions have been ruled out. Management of CDGP may involve expectant observation or therapy with low-dose sex steroids. [9]
- B. Initial authorization of 6 months, and reauthorization of 12 months is based on the Endocrine Society's Clinical Practice Guideline's recommendation to monitor testosterone level 3 to 6 months after initiation of testosterone therapy, and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering from any adverse effects. [8]
- C. The gender criteria in place for male hypogonadism, delayed puberty, and inoperable breast cancer are to ensure safe and effective medication utilization due to FDA-approved labeling supporting the gender restriction [Refer to individual package inserts]. Age and/or gender criteria will remain in the guideline, consistent with the following direction approved by OptumRx Legal & Regulatory: "Age and gender edits in place due to FDA safety guidance, labeling or supported by medical literature to satisfy medical necessity criteria would not be inconsistent with the [Section 1557 HCR non-discrimination] regulation."
- D. According to DRUGDEX, for the treatment of transgender male (female-to-male) patients with gender dysphoria, various forms and dosages of testosterone have been used. [13] Clinical studies have also demonstrated the efficacy of several different androgen preparations to induce masculinization in female-to-male transsexual persons. Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism. Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range. [11]
- E. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal center [19-20].
- F. Per consult with specialist, the pharmacokinetics of T. cypionate and T. enanthate are quite similar and physiologically produce similar results. The two agents are very close in

efficacy and behavioral effects. Although T. cypionate isn't FDA-approved for delayed puberty, it is used in practice due to its similarity to T. enanthate. [25]

4 . References

1. Androderm Prescribing Information. Allergan Inc. Madison, NJ. May 2020.
2. Androgel Prescribing Information. Abbvie, Inc. North Chicago, IL. May 2019.
3. Androgel 1.62% Prescribing Information. AbbVie Inc. North Chicago, IL. February 2019.
4. Fortesta Prescribing Information. Endo Pharmaceuticals. Malvern, PA. June 2020.
5. Methitest Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. October 2018.
6. Testim Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. November 2020.
7. Mulhall JP, Trost LW, Brannigan RE, et al. Evaluation and management of testosterone deficiency: AUA guideline. *J Urol* 2018; S0022-5347(18)42817-0.
8. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab* 2018; 103(5):1715-1744.
9. Palmert MR, Dunkel L. Clinical practice. Delayed puberty. *N Engl J Med*. 2012; 2;366(5):443-53.
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11. Hembree, Wylie C, et al. "Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline." *J Clin Endocrinol Metab*. November 2017, 102(11):3869-3903.
12. DRUGDEX ® [Internet database]. Greenwood Village, Colo: Thomson MICROMEDEX, updated periodically. Accessed February 7, 2022.
13. Natesto Prescribing Information. Trimel BioPharma SRL. Eaglewood, CO. September 2017.
14. Testosterone Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.
15. Testosterone Pump Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.
16. Methyltestosterone Prescribing Information. Impax Generics. Hayward, CA. January 2017.
17. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *International Journal of Transgenderism*. 13:165-232, 2011.
18. Depo-Testosterone Prescribing information. Pfizer. New York, NY. November 2018.
19. Testosterone Enanthate Prescribing Information. Actavis Pharma, Inc. Corona, CA. December 2017.
20. Testopel Prescribing Information. Slate Pharma. Rye, NY. August 2018.
21. Aveed Prescribing Information. Endo Pharmaceuticals Solutions Inc. August 2021.
22. Testone CIK Prescribing Information. Asclemed USA, Inc. Torrance, CA. November 2018.
23. Xyosted Prescribing Information. Antares Pharma, Inc. Ewing, NJ. November 2019.
24. Jatenzo Prescribing Information. Clarus Therapeutics, Inc. Northbrook, IL. June 2019.
25. Per clinical consultation with endocrinology specialist, March 02, 2020.

26. World Health Organization. ICD-11: International classification of diseases (11th revision).
27. Tlando Prescribing Information. Antares Pharma, Inc. Ewing, NJ. March 2022.
28. Deutsch, MB, Amato P, Coureu M, et al. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. UCSF Gender Affirming Health Program, Department of Family and Community Medicine, University of California San Francisco. June 2016
29. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.137(3):e75-e88, 2021
30. Kyzatrex Prescribing Information. Marius Pharmaceuticals. Raleigh, NC. July 2022.

Prior Authorization Guideline

Guideline Name	Tezspire (tezepelumab-ekko) - PA
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Tezspire (tezepelumab-ekko) injection, for subcutaneous use
Severe Asthma Indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. Limitations of Use: Tezspire is not indicated for the relief of acute bronchospasm or status asthmaticus.

2 . Criteria

Product Name: Tezspire	
Approval Length	6 Month(s) [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of severe asthma	

AND

2 - Patient is 12 years of age or older

AND

3 - One of the following: [2,3]

- Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months
- Prior asthma-related hospitalization within the past 12 months

AND

4 - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:

4.1 Both of the following: [2,3]

- High-dose inhaled corticosteroid (ICS) (i.e., greater than 500 mcg fluticasone propionate equivalent/day)
- Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol], Breo Ellipta [fluticasone/vilanterol]) [B]

AND

5 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Allergist/Immunologist

Product Name: Tezspire	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following:</p> <ul style="list-style-type: none"> • A reduction in asthma exacerbations • Improvement in forced expiratory volume in 1 second (FEV1) from baseline <p style="text-align: center;">AND</p> <p>2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [4]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Pulmonologist • Allergist/Immunologist 	

3 . Endnotes

- A. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, after initiation of treatment, patients should be re-evaluated in 3 to 6 months. [4]
- B. The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention guideline recommend patients with severe asthma should be treated with maximal optimized high dose ICS-LABA therapy. [4]

4 . References

1. Tezspire (tezepelumab-ekko) Prescribing Information. Amgen Inc, Thousand Oaks, CA. February 2023
2. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in Adults and Adolescents with Severe, Uncontrolled Asthma. *N Engl J Med.* 2021;384(19):1800-1809.
3. Corren J, Parnes JR, Wang L, et al. Tezepelumab in Adults with Uncontrolled Asthma. *N Engl J Med.* 2017;377(10):936-946.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2021 update). 2021 www.ginasthma.org. Accessed February 2021.

Thalomid (thalidomide)

Prior Authorization Guideline

Guideline Name	Thalomid (thalidomide)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 months [1, 8]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of moderate to severe erythema nodosum leprosum (ENL) with cutaneous manifestations AND 2 - Thalomid is not used as monotherapy if moderate to severe neuritis is present	

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)
Approval Length	12 months [1, 8]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to Thalomid therapy</p>	

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of multiple myeloma</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with dexamethasone, unless the patient has an intolerance to steroids</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist/hematologist</p>	

Product Name: Thalomid	
Diagnosis	Multiple Myeloma

Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Thalomid therapy	

2 . References

1. Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2017.

Prior Authorization Guideline

Guideline Name	Tibsovo (ivosidenib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Tibsovo (ivosidenib)
Newly-Diagnosed Acute Myeloid Leukemia (AML) Indicated in combination with azacitidine or as monotherapy for the treatment of newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
Relapsed or Refractory Acute Myeloid Leukemia (AML) Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
Locally Advanced or Metastatic Cholangiocarcinoma Indicated for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name: Tibsovo

Diagnosis	Newly-Diagnosed Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of newly-diagnosed acute myeloid leukemia (AML)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p> 3.1 Patient is greater than or equal to 75 years old</p> <p style="text-align: center;">OR</p> <p> 3.2 Patient has comorbidities that preclude use of intensive induction chemotherapy [A]</p>	

Product Name: Tibsovo	
Diagnosis	Relapsed or Refractory Acute Myeloid Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name: Tibsovo	
Diagnosis	Locally Advanced or Metastatic Cholangiocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of cholangiocarcinoma	
AND	
2 - Disease is one of the following:	
<ul style="list-style-type: none">• Locally Advanced• Metastatic	
AND	

3 - Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

4 - Patient has been previously treated

Product Name: Tibsovo	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

- A. Examples of comorbid conditions are severe cardiac or pulmonary disease, baseline ECOG performance status greater than or equal to 2, hepatic impairment with bilirubin greater than 1.5 times the upper limit of normal, or creatinine clearance less than 45 mL/min. [1]

4 . References

1. Tibsovo prescribing information. Servier Pharmaceuticals LLC, Boston, MA. June 2022.
2. U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/cm301431.htm>. Accessed June 15, 2022.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. Version 2.2022. Accessed June 15, 2022.

Prior Authorization Guideline

Guideline Name	Tier Lowering Exceptions Process
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Tier Lowering Exceptions Process	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - A prescribed drug will be considered for coverage under the prescribed drug's lower tier when one of the following are met:</p> <p>1.1 All lower-tiered medication alternatives would be less effective or have been demonstrated to be ineffective for treating the patient's condition when used at optimized dose and frequency</p> <p style="text-align: center;">OR</p>	

1.2 All lower-tiered medication alternatives would have adverse effects (intolerance or contraindication) in the treatment of the patient's condition.

Prior Authorization Guideline

Guideline Name	Tobramycin Inhaled Products - ST, NF
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Guideline Note:

Effective Date:	6/15/2022
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1 . Indications

Drug Name: Bethkis (tobramycin) Inhalation Solution
Cystic Fibrosis Indicated for the management of cystic fibrosis patients with <i>Pseudomonas aeruginosa</i> . Safety and efficacy have not been demonstrated in patients under the age of six years, patients with FEV ₁ less than 40% or greater than 80% predicted, or patients colonized with <i>Burkholderia cepacia</i> .
Drug Name: Kitabis Pak (co-packaged tobramycin inhalation solution PARI LC PLUS reusable nebulizer)
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with <i>P. aeruginosa</i> . Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV ₁ less than 25% or greater than 75% predicted, or patients colonized with <i>Burkholderia cepacia</i>
Drug Name: TOBI (tobramycin) Inhalation Solution
Cystic fibrosis Indicated for the management of cystic fibrosis in adults and pediatric patients 6 years of age and older with <i>Pseudomonas aeruginosa</i> . Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV ₁ less than 25% or greater than 75% predicted, or patients colonized with <i>Burkholderia cepacia</i>

2 . Criteria

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of a minimum 30 day supply, or intolerance to both of the following:</p> <ul style="list-style-type: none">• generic tobramycin 300 mg/4 ml nebulized solution• generic tobramycin 300 mg/5 ml nebulized solution	

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure of a minimum 30 day supply, or intolerance to both of the following:</p> <ul style="list-style-type: none">• generic tobramycin 300 mg/4 ml nebulized solution• generic tobramycin 300 mg/5 ml nebulized solution	

3 . References

1. Kitabis Pak Prescribing Information. Catalent Pharma Solutions, LLC. Woodstock, IL. November 2019.
2. TOBI Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. October 2018.
3. Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. November 2020.

Prior Authorization Guideline

Guideline Name	Topical Retinoid Agents
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Guideline Note:

Effective Date:	5/15/2022
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1 . Indications

Drug Name: Tretinoin
<p>Acne vulgaris Indicated for the treatment of acne vulgaris</p> <p>Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease wound healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.</p> <p>Actinic keratosis [9]</p> <p>Hyperkeratosis [9]</p> <p>Keloid scar [9]</p>
Drug Name: Akliel (trifarotene) cream
<p>Acne vulgaris Indicated for the treatment of acne vulgaris in patients 9 years of age and older.</p>
Drug Name: Atralin (tretinoin), Avita (tretinoin) cream and gel, Retin-A (tretinoin) cream and gel, Retin-A Micro (tretinoin) gel, Altreno (tretinoin lotioni 0.05%)

Acne vulgaris Indicated for the treatment of acne vulgaris.
Drug Name: Differin (adapalene) cream/lotion/gel
Acne vulgaris Indicated for the treatment of acne vulgaris.

2 . Criteria

Product Name: Brand Avita, Generic Adapalene 0.3% (gel), Generic Tretinoin, or Generic Tretinoin Microsphere	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acne vulgaris (i.e., acne)	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Akliel, Brand Atralin, Brand Differin lotion 0.1%, Brand Differin gel 0.3%, Brand Retin-A, Brand Retin-A Micro, Brand Adapalene 0.1% Soln, Brand Altreno	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acne vulgaris (i.e., acne)	
AND	

2 - History of failure, contraindication, or intolerance to three formulary retinoid products (e.g., Avita cream or gel, Tretinoin cream or gel)

Notes

Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Brand Avita, Generic Tretinoin, Generic Tretinoin Microsphere

Diagnosis

Other Medical Uses (Off-Label)

Approval Length

12 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [A, 9]

- Actinic keratosis
- Hyperkeratosis
- Keloid scar
- Wound healing (mild)

Notes

Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Brand Atralin, Brand Retin-A, Brand Retin-A Micro, Brand Altreno

Diagnosis

Other Medical Uses (Off-Label)

Approval Length

12 month(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [A, 9]

- Actinic keratosis
- Hyperkeratosis
- Keloid Scar

- Wound healing (mild)

AND

2 - History of failure, contraindication, or intolerance to three formulary retinoid products (e.g., Avita cream or gel, Tretinoin cream or gel)

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]
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3 . Background

Clinical Practice Guidelines	
The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions) [10]	
Uses	Medical vs. Cosmetic
Actinic keratosis	Medical
Chloasma	Cosmetic
Fine wrinkles on face	Cosmetic
Hyperkeratosis	Medical
Hyperpigmentation of skin, Facial mottling	Cosmetic
Keloid scar	Medical
Roughness of skin, Facial tactile roughness	Cosmetic
Ultraviolet-induced change in normal skin	Cosmetic
Wound healing (mild)	Medical

4 . Endnotes

- A. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions). [10] Please refer to Background section for table with details.

5 . References

1. Adapalene Topical Solution 0.1% Prescribing Information. Rochester Pharmaceuticals. December 2020.
2. Akliel Prescribing Information. Galderma Laboratories, L.P. Fort Worth, Texas. October 2019.
3. Altreno Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. March 2020.
4. Atralin prescribing information. Valeant Pharmaceuticals. Bridgewater, NJ. July 2016.
5. Avita prescribing information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2018.
6. Differin prescribing information. Galderma Laboratories, L.P. Fort Worth, TX. February 2018.
7. Retin-A prescribing information. Bausch Health US, LLC. Bridgewater, NJ. September 2019.
8. Retin-A Micro prescribing information. Valeant Pharmaceuticals. Bridgewater, NJ. October 2017.
9. DRUGDEX System [Internet database]. Greenwood Village (CO): IBM Corporation; Updated periodically. Available by subscription at: www.micromedexsolutions.com. Accessed November 12, 2021
10. Per clinical consult with dermatologist, June 7, 2012.

Tremfya (guselkumab)

Prior Authorization Guideline

Guideline Name	Tremfya (guselkumab)
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Guideline Note:

Effective Date:	4/13/2022
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1 . Indications

Drug Name: Tremfya (guselkumab)
Plaque Psoriasis Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis.

2 . Criteria

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate-to-severe plaque psoriasis

AND

2 - Prescribed by or in consultation with a dermatologist

Product Name: Tremfya

Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [2]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Tremfya

Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA) [1, 3]

AND

2 - Prescribed by or in consultation with one of the following:

- Dermatologist
- Rheumatologist

Product Name: Tremfya

Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . References

1. Tremfya prescribing information. Janssen Biotech, Inc. Horsham, PA. July 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol 2019;80:1029-72.
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.

Prior Authorization Guideline

Guideline Name	Trikafta (elexacaftor/tezacaftor/ivacaftor)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Trikafta (elexacaftor/tezacaftor/ivacaftor)
Cystic Fibrosis Indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on in vitro data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on in vitro data.

2 . Criteria

Product Name: Trikafta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - One of the following:

- For granule packets, patient is at least 2 to less than 6 years of age
- For tablets, patient is 6 years of age or older

AND

3 - Patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as detected by a FDA-cleared cystic fibrosis mutation test or a test performed at a Clinical Laboratory Improvement Amendments (CLIA)-approved facility:*

- F508del mutation
- A mutation in the CFTR gene that is responsive based on in vitro data

AND

4 - Prescribed by or in consultation with one of the following:

- Pulmonologist
- Specialist affiliated with a CF care center

Notes

*Please consult Background section for table of CFTR gene mutations responsive to Trikafta.

Product Name: Trikafta

Approval Length | 12 month(s)

Therapy Stage | Reauthorization

Guideline Type | Prior Authorization

Approval Criteria

1 - Documentation of a positive clinical response to therapy (e.g., improvement in lung function [percent predicted forced expiratory volume in one second {PPFEV1}] or decreased number of pulmonary exacerbations) [1,2]

3 . Background

Clinical Practice Guidelines

CFTR Mutations that are responsive to Trikafta

*Intent of table is to provide a quick reference; PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 10/31/22]

List of CFTR Gene Mutations that are Responsive to Trikafta

<i>3141del9</i>	<i>E822K</i>	<i>G1069 R</i>	<i>L967S</i>	<i>R117L</i>	<i>S912L</i>
<i>546insCTA</i>	<i>F191V</i>	<i>G1244 E</i>	<i>L997F</i>	<i>R117P</i>	<i>S945L</i>
<i>A46D</i>	<i>F311del</i>	<i>G1249 R</i>	<i>L1077P</i>	<i>R170H</i>	<i>S977F</i>
<i>A120T</i>	<i>F311L</i>	<i>G1349 D</i>	<i>L1324P</i>	<i>R258G</i>	<i>S1159F</i>
<i>A234D</i>	<i>F508C</i>	<i>H139R</i>	<i>L1335P</i>	<i>R334L</i>	<i>S1159P</i>
<i>A349V</i>	<i>F508C;S1251 N †</i>	<i>H199Y</i>	<i>L1480P</i>	<i>R334Q</i>	<i>S1251N</i>
<i>A455E</i>	<i>F508del *</i>	<i>H939R</i>	<i>M152V</i>	<i>R347H</i>	<i>S1255P</i>
<i>A554E</i>	<i>F575Y</i>	<i>H1054 D</i>	<i>M265R</i>	<i>R347L</i>	<i>T338I</i>
<i>A1006E</i>	<i>F1016S</i>	<i>H1085 P</i>	<i>M952I</i>	<i>R347P</i>	<i>T1036N</i>
<i>A1067T</i>	<i>F1052V</i>	<i>H1085 R</i>	<i>M952T</i>	<i>R352Q</i>	<i>T1053I</i>

D110E	F1074L	H1375 P	M1101K	R352W	V201M
D110H	F1099L	I148T	P5L	R553Q	V232D
D192G	G27R	I175V	P67L	R668C	V456A
D443Y	G85E	I336K	P205S	R751L	V456F
D443Y;G576A;R668 C †	G126D	I502T	P574H	R792G	V562I
D579G	G178E	I601F	Q98R	R933G	V754M
D614G	G178R	I618T	Q237E	R1066 H	V1153E
D836Y	G194R	I807M	Q237H	R1070 Q	V1240 G
D924N	G194V	I980K	Q359R	R1070 W	V1293 G
D979V	G314E	I1027T	Q1291R	R1162L	W361R
D1152H	G463V	I1139V	R31L	R1283 M	W1098 C
D1270N	G480C	I1269N	R74Q	R1283S	W1282 R
E56K	G551D	I1366N	R74W	S13F	Y109N
E60K	G551S	K1060 T	R74W;D1270N †	S341P	Y161D
E92K	G576A	L15P	R74W;V201M †	S364P	Y161S
E116K	G576A;R668 C †	L165S	R74W;V201M;D1270 N †	S492F	Y563N
E193K	G622D	L206W	R75Q	S549N	Y1014C
E403D	G628R	L320V	R117C	S549R	Y1032C
E474K	G970D	L346P	R117G	S589N	
E588V	G1061R	L453S	R117H	S737F	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

4 . References

1. Trikafta Prescribing information. Vertex Pharmaceuticals Inc. Boston, MA. April 2023.
2. Keating D, Marigowda G, Burr L, et al. VX-445–tezacaftor–ivacaftor in patients with cystic fibrosis and one or two Phe508del alleles. *N Engl J Med.* 2018;379:1612-20.

Trintellix (vortioxetine)

Prior Authorization Guideline

Guideline Name	Trintellix (vortioxetine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Trintellix	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria 1 - Trial and failure, contraindication, or intolerance to any of the following generics: <ul style="list-style-type: none">• desvenlafaxine succinate extended-release (ER)• duloxetine• venlafaxine• venlafaxine ER <p style="text-align: center;">OR</p>	

2 - For continuation of prior therapy

Prior Authorization Guideline

Guideline Name	Trogarzo (ibalizumab-uiyk)- PA, NF
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Guideline Note:

Effective Date:	5/1/2022
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1 . Indications

Drug Name: Trogarzo (ibalizumab-uiyk)
Multidrug Resistant HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen.

2 . Criteria

Product Name: Trogarzo	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - One of the following:	

1.1 All of the following:

1.1.1 Diagnosis of HIV-1 infection

AND

1.1.2 HIV-1 infection is multidrug resistant as confirmed by a resistance assay

AND

1.1.3 Patient is currently taking, or will be prescribed, an optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 For continuation of prior therapy

Product Name: Trogarzo	
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - One of the following:	
1.1 All of the following:	
1.1.1 Diagnosis of HIV-1 infection	

AND

1.1.2 HIV-1 infection is multidrug resistant as confirmed by a resistance assay

AND

1.1.3 Patient is currently taking, or will be prescribed, an optimized background antiretroviral therapy regimen

AND

1.1.4 Prescribed by or in consultation with a clinician with HIV expertise

OR

1.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than 45-day gap in therapy

3 . References

1. Trogarzo Prescribing Information. Theratechnologies Inc. Montreal, Quebec Canada. September 2021.

Truseltiq (infigratinib)

Prior Authorization Guideline

Guideline Name	Truseltiq (infigratinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Truseltiq (infigratinib)
Cholangiocarcinoma Indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

2 . Criteria

Product Name: Truseltiq	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of cholangiocarcinoma

AND

2 - Disease is one of the following:

- Unresectable locally advanced
- Metastatic

AND

3 - Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

4 - Patient has been previously treated

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Oncologist

Product Name: Truseltiq

Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Truseltiq Prescribing Information. QED Therapeutics, Inc. Brisbane, CA. May 2021.

Prior Authorization Guideline

Guideline Name	Tukysa (tucatinib)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Tukysa (tucatinib)
<p>Breast Cancer Indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.</p> <p>Colorectal cancer Indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type, HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.</p>

2 . Criteria

Product Name: Tukysa	
Diagnosis	Breast Cancer
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Advanced unresectable • Metastatic <p style="text-align: center;">AND</p> <p>3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive</p> <p style="text-align: center;">AND</p> <p>4 - Used in combination with trastuzumab and capecitabine</p> <p style="text-align: center;">AND</p> <p>5 - Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)</p> <p style="text-align: center;">AND</p> <p>6 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Tukysa	
Diagnosis	Colorectal Cancer

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of colorectal cancer

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Patient has RAS wild-type tumors

AND

5 - Used in combination with trastuzumab

AND

6 - Patient has progressed following treatment with ONE of the following:

- Fluoropyrimidine-based chemotherapy
- Oxaliplatin-based chemotherapy
- Irinotecan-based chemotherapy

AND

7 - Prescribed by or in consultation with an oncologist

Product Name: Tukysa

Diagnosis	All indications listed above
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

1. Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. January 2023.

Turalio (pexidartinib)

Prior Authorization Guideline

Guideline Name	Turalio (pexidartinib)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Turalio (pexidartinib)
Tenosynovial Giant Cell Tumor (TGCT) Indicated for the treatment of adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

2 . Criteria

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of tenosynovial giant cell tumor (TGCT)	

AND
2 - Patient is symptomatic
AND
3 - Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal
AND
4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Turalio	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Turalio prescribing information. Daiichi Sankyo, Inc. Basking Ridge, NJ. October 2022.

Tykerb (lapatinib)

Prior Authorization Guideline

Guideline Name	Tykerb (lapatinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Tykerb (lapatinib)
Metastatic breast cancer (1) In combination with Xeloda (capecitabine), indicated for the treatment of patients with advanced or metastatic breast cancer whose tumors over-express HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab; (2) In combination with Femara (letrozole), indicated for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.
Off Label Uses: HER2-positive Breast Cancer [4-6] Used for the first-line treatment of HER2-positive locally-advanced or metastatic breast cancer.

2 . Criteria

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of HER2-positive metastatic or recurrent breast cancer [2-6]</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with one of the following: [3]</p> <ul style="list-style-type: none"> • Trastuzumab • Xeloda (capecitabine) • Aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimedex (anastrozole)] <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease</p>	

3 . References

1. Tykerb Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. December 2018.
2. Geyer CE, Forster J, Lindquist D, et al. Lapatinib plus capecitabine for HER2-positive advanced breast cancer. N Engl J Med. 2006;355(26):2733-2743.
3. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium. National Comprehensive Cancer Network, Inc. 2020. Accessed August 12, 2020.

4. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 12, 2020.
5. Moy B, Goss PE. Lapatinib: current status and future directions in breast cancer. *Oncologist*. 2006;11:1047-57.
6. Gomez H, Doval D, Chavez M, et al. Efficacy and safety of lapatinib as first-line therapy for ErbB2-amplified locally advanced or metastatic breast cancer. *J Clin Oncol*. 2008 May 5 [Epub ahead of print].
7. Lapatinib Prescribing Information. Lupin Pharmaceuticals, Inc. Baltimore, MD. September 2020.

Tymlos (abaloparatide injection)

Prior Authorization Guideline

Guideline Name	Tymlos (abaloparatide injection)
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Guideline Note:

Effective Date:	8/1/2023
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1 . Indications

Drug Name: Tymlos (abaloparatide injection)
Postmenopausal women with osteoporosis at high risk of fracture Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos reduces the risk of vertebral fractures and nonvertebral fractures.
Increase Bone Density in Men with Osteoporosis at High Risk for Fracture Indicated to increase bone density in men with osteoporosis at high risk for fracture (defined as a history of osteoporotic fracture or multiple risk factors for fracture), or patients who have failed or are intolerant to other available osteoporosis therapy.

2 . Criteria

Product Name: Tymlos	
Approval Length	24 month(s)*
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Postmenopausal osteoporosis or osteopenia

OR

1.2 Primary or hypogonadal osteoporosis or osteopenia

AND

2 - One of the following: [2,4,5]

2.1 For diagnosis of osteoporosis, both of the following:

2.1.1 Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.1.2 One of the following:

2.1.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.1.2.2 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

OR

2.2 For diagnosis of osteopenia, both of the following:

2.2.1 BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site)

AND

2.2.2 One of the following:

2.2.2.1 History of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm

OR

2.2.2.2 Both of the following:

2.2.2.2.1 Trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab])

AND

2.2.2.2.2 One of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: [A]

- Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions
- Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions

AND

3 - Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime [1,2]

Notes

Parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) not to exceed the FDA-recommended treatment duration of 2 years. *Tymlos will not be approved if the patient has already received 24 months of therapy; if the patient has not yet received 24 months of therapy, approval may be granted for the balance of the time remaining.

3 . Definitions

Definition	Description
Osteopenia [3]	The designation for bone density between 1.0 and 2.5 standard deviations below the mean for young normal adults (T-score between -1 and -2.5).
Osteoporosis [3]	A chronic, progressive disease characterized by low bone mass, microarchitectural deterioration and decreased bone strength, bone fragility and a consequent increase in fracture risk; bone density 2.5 or more standard deviations below the young normal mean (T-score at or below -2.5).
T-score [3]	In describing bone mineral density, the number of standard deviations above or below the mean for young normal adults of the same sex.

4 . Endnotes

- A. The WHO FRAX tool is available at www.shef.ac.uk/FRAX and incorporates multiple clinical factors that predict fracture risk, largely independent of BMD. [2]

5 . References

1. Tymlos prescribing information. Radius Health, Inc. Waltham, MA. December 2022.
2. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal osteoporosis: 2020 update. Available at: <https://pro.aace.com/disease-state-resources/bone-and-parathyroid/clinical-practice-guidelines/clinical-practice>. Accessed May 6, 2021.
3. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Washington (DC): National Osteoporosis Foundation; 2013.
4. Per clinical consultation with endocrinologists. January 23 & 30, 2018.
5. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2019; 104(5):1595-1622.
6. Watts NB, Adler RA, Bilezikian JP, et al. Endocrine Society. Osteoporosis in men: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2012;97(6):1802-22.

Tyrvaya (varenicline solution)

Prior Authorization Guideline

Guideline Name	Tyrvaya (varenicline solution)
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Guideline Note:

Effective Date:	5/15/2022
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1 . Indications

Drug Name: Tyrvaya (varenicline solution) nasal spray
Dry Eye Disease Indicated for the treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name: Tyrvaya	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of dry eye disease confirmed by ONE of the following diagnostic tests: [A, 2-4]	
<ul style="list-style-type: none">• Schirmer test	

- Ocular surface dye staining (e.g., rose bengal, fluorescein, lissamine green)
- Tear function index/fluorescein clearance test
- Tear break up time
- Tear film osmolarity
- Slit lamp lid evaluation
- Lacrimal gland function

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to at least one OTC ocular lubricant (e.g., artificial tears, lubricating gels/ointments) [B, 2-4]

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

- Restasis (cyclosporine 0.05%)
- Xiidra (lifitegrast)

AND

4 - Prescribed by or in consultation with one of the following:

- Ophthalmologist
- Optometrist

Product Name: Tyrvaya	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)	

3 . Endnotes

- A. Traditional diagnostic tests include the Schirmer test, ocular surface dye staining, tear function index/fluorescein clearance test, tear break up time, tear film osmolarity, slit lamp evaluation of lid [2-4]
- B. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (e.g., emulsions, gels, ointments). Anti-inflammatory therapies (e.g., topical cyclosporine, corticosteroids), systemic omega-3 fatty acid supplements, punctal plugs, and eyeglass side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management [2-4]

4 . References

1. Tyrvaya Prescribing Information. Oyster Point Pharma, Inc. Princeton, NJ. October 2021.
2. American Academy of Ophthalmology. Dry Eye Syndrome Preferred Practice Pattern. October 2018. Available at [https://www.aaojournal.org/article/S0161-6420\(18\)32650-2/fulltext#tbl3](https://www.aaojournal.org/article/S0161-6420(18)32650-2/fulltext#tbl3). Accessed November 4, 2021.
3. Wood, S., Mian, S. Diagnostic Tools for Dry Eye Disease. Available at https://www.touchophthalmology.com/wp-content/uploads/sites/16/2017/01/Diagnostic-Tools-for-Dry-Eye-Disease_1.pdf. Accessed Nov 9. 2021.
4. Zeev, M., Miller, D, et al. Diagnosis of dry eye disease and emerging technologies. Clin Ophthalmol 2014;8:581-590. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3964175/#b16-opth-8-581>. Accessed November 9, 2021.

Tysabri (natalizumab)

Prior Authorization Guideline

Guideline Name	Tysabri (natalizumab)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Tysabri (natalizumab)

Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. Tysabri increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with Tysabri, physicians should consider whether the expected benefit of Tysabri is sufficient to offset this risk.

Crohn's Disease (CD) Indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active CD with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-alpha. In CD, Tysabri should not be used in combination with immunosuppressants (e.g., 6-mercaptopurine, azathioprine, cyclosporine, or methotrexate) or inhibitors of TNF-alpha.

2 . Criteria

Product Name: Tysabri

Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting MS, secondary-progressive disease, including active disease with new brain lesions) [B]

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Aubagio (teriflunomide)*
- Avonex (interferon beta-1a)*
- Copaxone/Glatopa (glatiramer acetate)*
- Extavia (interferon beta-1b)*^
- Gilenya (fingolimod)*
- Kesimpta (ofatumumab)*
- Plegridy (peginterferon beta-1a)*
- dimethyl fumarate*
- Zeposia (ozanimod)*

OR

2.2 Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis [2]

OR

2.3 For continuation of prior therapy [2]

AND	
3 - Not used in combination with another disease-modifying therapy for MS	
AND	
4 - Prescribed by or in consultation with a neurologist	
Notes	*These products may require Prior Authorization. ^Product may be excluded depending on the plan.

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)</p> <p style="text-align: center;">AND</p> <p>2 - Not used in combination with another disease-modifying therapy for MS</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Tysabri	
Diagnosis	Crohn's Disease (CD)

Approval Length	3 Months [1]**
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active Crohn's disease

AND

2 - Crohn's disease has evidence of inflammation (e.g., elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes)

AND

3 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies [3, 7]:

- corticosteroids (e.g., prednisone)
- 6-mercaptopurine
- azathioprine
- methotrexate

AND

4 - Trial and failure, contraindication, or intolerance to a tumor necrosis factor (TNF)-inhibitor (e.g., Cimzia [certolizumab pegol], Humira [adalimumab], infliximab)

AND

5 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

6 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab], or infliximab) [A, C]

AND

7 - Prescribed by or in consultation with a gastroenterologist

Notes

**In CD, discontinue Tysabri in patients that have not experienced the therapeutic benefit by 12 weeks of induction therapy, and in patients that cannot discontinue chronic concomitant steroids within six months of starting therapy. [1]

Product Name: Tysabri

Diagnosis Crohn's Disease (CD)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by at least one of the following [1, 3, 7]:

- Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline
- Reversal of high fecal output state

AND

2 - Not used in combination with an immunosuppressant (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) [A, C]

AND

3 - Not used in combination with a TNF-inhibitor (e.g., Enbrel [etanercept], Humira [adalimumab], or infliximab) [A, C]

3 . Endnotes

- A. To minimize the risk of progressive multifocal leukoencephalopathy, natalizumab must be administered as a monotherapy without concomitant immunosuppressive therapy. Aminosalicylates may be continued during treatment with Tysabri. [1, 3]
- B. Of the four disease courses of MS, relapse-remitting MS (RRMS) is characterized primarily by relapse, while secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. Most patients with RRMS eventually develop SPMS. As a person transitions from RRMS to SPMS, the disease begins to worsen more steadily, with or without occasional relapses, slight remissions, or plateaus. As long as the patient continues to have relapses, the SPMS course is considered to be both progressive and relapsing. [4]
- C. In the postmarketing setting, additional cases of PML have been reported in multiple sclerosis and Crohn's disease patients who were receiving no concomitant immunomodulatory therapy. Three factors that are known to increase the risk of PML in TYSABRI-treated patients have been identified: 1) Longer treatment duration, especially beyond 2 years. There is limited experience in patients who have received more than 4 years of TYSABRI treatment. 2) Prior treatment with an immunosuppressant (e.g., mitoxantrone, azathioprine, methotrexate, cyclophosphamide, mycophenolate mofetil). 3) The presence of anti-JCV antibodies. Patients who are anti-JCV antibody positive have a higher risk for developing PML. [1]

4 . References

1. Tysabri Prescribing Information. Biogen Inc. Cambridge, MA. December 2021.
2. Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurology* 2018;90:777-788.
3. Lichtenstein GR, Loftus EV, Isaacs KL, et al. Management of Crohn's disease in adults. *Am J Gastroenterol.* 2018;113:481-517.
4. National Multiple Sclerosis Society. Types of MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Types-of-MS>. Accessed April 11, 2022.
5. FDA Drug Safety Communication: New risk factor for progressive multifocal leukoencephalopathy (PML) associated with Tysabri (natalizumab). January 20, 2012. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm288186.htm>. Accessed April 11, 2022.
6. Nelson SML, Nguyen TM, McDonald J, MacDonald JK. Natalizumab for induction of remission in Crohn's disease. *Cochrane Database of Systematic Reviews* 2018, Issue 8. Art. No.: CD006097. DOI: 10.1002/14651858.CD006097.pub3.
7. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. *Gastroenterology.* 2021;160(7):2496-2508.

Ukoniq (umbralisib)

Prior Authorization Guideline

Guideline Name	Ukoniq (umbralisib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Ukoniq (umbralisib)
Marginal zone lymphoma (MZL) Indicated for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen.
Follicular lymphoma (FL) Indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

2 . Criteria

Product Name: Ukoniq	
Diagnosis	Marginal Zone Lymphoma (MZL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of marginal zone lymphoma (MZL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least one prior anti-CD20-based regimen (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ukoniq	
Diagnosis	Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of follicular lymphoma (FL)	
AND	

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient has received at least three prior lines of systemic therapy (e.g., bendamustine + rituximab, bendamustine + obinutuzumab, etc.)

AND

4 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Ukoniq	
Diagnosis	Marginal Zone Lymphoma (MZL), Follicular Lymphoma (FL)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Ukoniq prescribing Information. TG Therapeutics, Inc. Edison, NJ. February 2021.

Uloric (febuxostat)

Prior Authorization Guideline

Guideline Name	Uloric (febuxostat)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Uloric	
Approval Length	12 month(s)
Guideline Type	Step Therapy
Approval Criteria 1 - History of an inadequate response, intolerance or contraindication to generic allopurinol or generic febuxostat <p style="text-align: center;">OR</p> 2 - Patient is not a candidate for generic allopurinol therapy or generic febuxostat	

2 . References

1. Khanna D, Fitzgerald JD, Khanna PP, et al. 2012 American College of Rheumatology Guidelines for management of gout. Part 1: Systematic nonpharmacologic and pharmacologic therapeutic approaches to hyperuricemia. Available at: https://www.rheumatology.org/Portals/0/Files/ACR%20Guidelines%20for%20Management%20of%20Gout_Part%201.pdf. Accessed on: 09.19.2017.
2. National Institute for Health and Care Excellence. Febuxostat for the management of hyperuricaemia in people with gout. Available at: <https://www.nice.org.uk/Guidance/TA164>. Accessed on: 09.19.2017.

Prior Authorization Guideline

Guideline Name	Ultomiris (ravulizumab-cwvz)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Ultomiris (ravulizumab-cwvz)
Paroxysmal Nocturnal Hemoglobinuria (PNH) Indicated for the treatment of patients one month of age and older with paroxysmal nocturnal hemoglobinuria (PNH).
Atypical Hemolytic Uremic Syndrome (aHUS) Indicated for the treatment of adults and pediatric patients one month of age and older with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA).
Generalized Myasthenia Gravis (gMG) Indicated for the treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive.

2 . Criteria

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is one month of age and older</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a hematologist/oncologist</p>	

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy</p>	

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of atypical hemolytic uremic syndrome (aHUS) [1]

AND

2 - Patient is one month of age and older

AND

3 - Prescribed by or in consultation with one of the following:

- Hematologist
- Nephrologist

Product Name: Ultomiris	
Diagnosis	Atypical Hemolytic Uremic Syndrome (aHUS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy	

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of generalized myasthenia gravis (gMG)

AND

2 - Patient is anti-acetylcholine receptor (AChR) antibody positive

AND

3 - One of the following: [2]

3.1 Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

OR

3.2 Both of the following:

3.2.1 Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)

AND

3.2.2 Trial and failure, contraindication, or intolerance to one of the following:

- Chronic plasmapheresis or plasma exchange (PE)
- Intravenous immunoglobulin (IVIG)

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Ultomiris	
Diagnosis	Generalized Myasthenia Gravis (gMG)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

3 . References

1. Ultomiris Prescribing Information. Alexion Pharmaceuticals, Inc. Boston, MA. April 2022.
2. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2016;87(4):419-25.

Unituxin (dinutuximab)

Prior Authorization Guideline

Guideline Name	Unituxin (dinutuximab)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Unituxin (dinutuximab)
Neuroblastoma Indicated, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy.

2 . Criteria

Product Name: Unituxin	
Diagnosis	Neuroblastoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of high-risk neuroblastoma

AND

2 - Used in combination with all of the following:

- Granulocyte-macrophage colony-stimulating factor (GM-CSF) [e.g., Leukine (sargramostim)]
- Interleukin-2 (IL-2) [e.g., Proleukin (aldesleukin)]
- 13-cis-retinoic acid (RA) [e.g., isotretinoin]

AND

3 - Patient responded to prior first-line multiagent, multimodality therapy (e.g., chemotherapy, surgery, stem cell transplant, radiation therapy)

AND

4 - Prescribed by a pediatric oncologist

3 . References

1. Unituxin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. September 2020.

Upneeq (oxymetazoline hydrochloride)

Prior Authorization Guideline

Guideline Name	Upneeq (oxymetazoline hydrochloride)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Upneeq (oxymetazoline hydrochloride ophthalmic solution)
Blepharoptosis Indicated for the treatment of acquired blepharoptosis in adults.

2 . Criteria

Product Name: Upneeq	
Diagnosis	Cosmetic Purposes
Guideline Type	Excluded Use
Approval Criteria	
1 - Requests for coverage of Upneeq when used solely for lifting the eyelid to improve appearance is not authorized and will not be approved. This use is considered cosmetic only.	

Product Name: Upneeq	
Diagnosis	Blepharoptosis
Approval Length	6 Week(s) [1, 4]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <ul style="list-style-type: none"> • Diagnosis of acquired blepharoptosis • Patient has obstructed visual field in primary gaze or down gaze due to blepharoptosis <p style="text-align: center;">AND</p> <p>2 - One of the following: [2]</p> <ul style="list-style-type: none"> • Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in primary gaze • Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze • Superior visual field loss of at least 12 degrees or 24 percent <p style="text-align: center;">AND</p> <p>3 - Other treatable causes of blepharoptosis have been ruled out (e.g., recent botulinum toxin injection, myasthenia gravis)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an ophthalmologist or optometrist</p>	

Product Name: Upneeq	
Diagnosis	Blepharoptosis
Approval Length	6 Week(s) [1, 4]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in superior visual field, increase in Marginal reflex distance-1 [MRD-1])

AND

2 - One of the following: [2]

- Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in primary gaze
- Marginal reflex distance-1 (MRD-1) is less than or equal to 2 mm in down gaze
- Superior visual field loss of at least 12 degrees or 24 percent

3 . References

1. Upneeq [package insert]. Bridgewater, NJ. RVL Pharmaceuticals, Inc. August 2020.
2. Cahill K, Bradley E, Meyer D et al. Functional Indications for Upper Eyelid Ptosis and Blepharoplasty Surgery. *Ophthalmology*. 2011;118(12):2510-2517.
3. Alsuhaibani A, Burkat C, Plemel D et al. Blepharoptosis - EyeWiki. *Eyewiki.aao.org*. <https://eyewiki.aao.org/Blepharoptosis>. Published 2020. Accessed August 31, 2020.
4. RVL Pharmaceuticals, Inc. Study of the Safety and Efficacy of RVL-1201 in the Treatment of Acquired Blepharoptosis. Available from: <https://clinicaltrials.gov/ct2/show/NCT02436759>. NCT02436759. Accessed September 10, 2020.
5. RVL Pharmaceuticals, Inc. Study of Safety and Efficacy of RVL-1201 in the Treatment of Blepharoptosis. Available from: <https://clinicaltrials.gov/ct2/show/NCT03565887>. NCT03565887. Accessed September 10, 2020.

Prior Authorization Guideline

Guideline Name	Urea Cycle Disorder Agents
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Buphenyl (sodium phenylbutyrate)
<p>Urea cycle disorders (UCDs) Indicated as adjunctive therapy in the chronic management of patients with urea cycle disorders involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). It is indicated in all patients with neonatal-onset deficiency (complete enzymatic deficiency, presenting within the first 28 days of life). It is also indicated in patients with late-onset disease (partial enzymatic deficiency, presenting after the first month of life) who have a history of hyperammonemic encephalopathy. It is important that the diagnosis be made early and treatment initiated immediately to improve survival. Any episode of acute hyperammonemia should be treated as a life-threatening emergency.</p>
Drug Name: Pheburane (sodium phenylbutyrate)
<p>Urea cycle disorders (UCDs) Indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS). Episodes of acute hyperammonemia may occur in patients while on Pheburane. Pheburane is not indicated for the treatment of acute hyperammonemia, which can be a life-threatening medical emergency that requires rapid acting interventions to reduce plasma ammonia levels.</p>
Drug Name: Ravicti (glycerol phenylbutyrate)

Urea cycle disorders (UCDs) Indicated for use as a nitrogen-binding agent for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements). Limitations of use: Ravicti is not indicated for the treatment of acute hyperammonemia in patients with UCDs because more rapidly acting interventions are essential to reduce plasma ammonia levels. The safety and efficacy of Ravicti for the treatment of N-acetylglutamate synthase (NAGS) deficiency has not been established.

Drug Name: Olpruva (sodium phenylbutyrate)

Urea cycle disorders (UCDs) Indicated for use as a nitrogen-binding agent, as an adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). Limitations of Use: Olpruva is not indicated for the treatment of acute hyperammonemia.

2 . Criteria

Product Name: Brand Buphenyl, generic sodium phenylbutyrate	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Diagnosis of urea cycle disorder (UCD)</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following deficiencies:</p> <ul style="list-style-type: none"> • carbamylphosphate synthetase (CPS) • ornithine transcarbamylase (OTC) 	

- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic sodium phenylbutyrate (applies to Brand Buphenyl only)

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Pheburane	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Diagnosis of urea cycle disorder (UCD)</p> <p>AND</p>	

1.2 One of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic sodium phenylbutyrate powder

AND

4 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

5 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Olpruva, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Both of the following:	
1.1 Diagnosis of urea cycle disorder (UCD)	

AND

1.2 One of the following deficiencies:

- carbamylphosphate synthetase (CPS)
- ornithine transcarbamylase (OTC)
- argininosuccinic acid synthetase (AS)

AND

2 - Molecular genetic testing confirms mutations in the CPS1, OTC, or ASS1 gene [2]

AND

3 - Inadequate response to one of the following:

- Dietary protein restriction
- Amino acid supplementation

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to generic sodium phenylbutyrate

AND

5 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)

AND

6 - Prescribed by or in consultation with a specialist focused on the treatment of metabolic disorders

Product Name: Brand Buphenyl, generic sodium phenylbutyrate, Olpruva, Pheburane, Ravicti	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., plasma ammonia and amino acid levels within normal limits)</p> <p style="text-align: center;">AND</p> <p>2 - Used as an adjunct with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements)</p>	

3 . References

1. Buphenyl Prescribing Information. Ucyclid Pharma, Inc. Scottsdale, AZ. April 2023.
2. Ah Mew N, Simpson KL, Gropman AL, et al. Urea Cycle Disorders Overview. 2003 [updated 2017]. In: Adam MP, Ardinger HH, Pagon RA, Wallace SE, Bean LJH, Gripp KW, Mirzaa GM, Amemiya A, eds. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993–2022. Urea Cycle Disorders Overview - GeneReviews® - NCBI Bookshelf (nih.gov). Accessed April 11, 2022.
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4. Ravicti [Prescribing Information]. Horizon Pharma USA, Inc. Lake Forest, IL. September 2021.
5. Pheburane Prescribing Information. Medunik USA, Inc. Bryn Mawr, PA. June 2022.
6. Olpruva Prescribing Information. Acer Therapeutics Inc.. Newton, MA. December 2022.
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Valchlor (mechlorethamine gel)

Prior Authorization Guideline

Guideline Name	Valchlor (mechlorethamine gel)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Valchlor (mechlorethamine gel)
Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) Indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

2 . Criteria

Product Name: Valchlor	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - One of the following diagnoses:	

- Stage IA mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL)
- Stage IB mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL)

AND

2 - Patient has received at least one prior skin-directed therapy (e.g., topical corticosteroids [e.g., clobetasol, fluocinonide], phototherapy, bexarotene topical gel [Targretin topical gel], etc.)

AND

3 - Prescribed by or in consultation with one of the following:

- Oncologist
- Dermatologist

Product Name: Valchlor	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Valchlor Prescribing Information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. January 2020.

Prior Authorization Guideline

Guideline Name	Vanflyta (quizartinib)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Vanflyta (quizartinib)
<p>Acute Myeloid Leukemia Indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. Limitations of Use: Vanflyta is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with Vanflyta in this setting has not been demonstrated.</p>

2 . Criteria

Product Name: Vanflyta	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML)

AND

2 - Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Both of the following:

- Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation
- Used as maintenance monotherapy following consolidation chemotherapy

Product Name: Vanflyta	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

1. Vanflyta Prescribing Information. Daiichi Sankyo, Inc., Basking Ridge. July 2023.
2. clinicaltrials.gov. Quizartinib With Standard of Care Chemotherapy and as Continuation Therapy in Patients With Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia (AML) (QuANTUM-First). Available at:

<https://clinicaltrials.gov/study/NCT02668653?term=nct02668653&rank=1>. Accessed August 29, 2023.

Venclexta (venetoclax)

Prior Authorization Guideline

Guideline Name	Venclexta (venetoclax)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Venclexta (venetoclax)
Chronic lymphocytic leukemia or Small lymphocytic lymphoma Indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Acute Myeloid Leukemia Indicated in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

2 . Criteria

Product Name: Venclexta	
Diagnosis	Chronic lymphocytic leukemia (CLL)/ Small Lymphocytic Lymphoma (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist • Oncologist 	

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of AML</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Newly diagnosed • Relapsed • Refractory <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p>	

- Hematologist
- Oncologist

Product Name: Venclexta	
Diagnosis	All indications listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Venclexta Prescribing Information. AbbVie, Inc. North Chicago, IL. June 2022.
2. National comprehensive cancer network (NCCN) clinical practice guidelines in oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.5.2019. Available from: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed June 4, 2019.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed on September 7, 2022.

Veozah (fezolinetant)

Prior Authorization Guideline

Guideline Name	Veozah (fezolinetant)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Veozah (fezolinetant)
Moderate to severe vasomotor symptoms Indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

2 . Criteria

Product Name: Veozah	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderate to severe vasomotor symptoms due to menopause	

AND

2 - Trial and failure, contraindication, or intolerance to both of the following:

- Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.)
- Non-hormonal therapy (e.g. paroxetine mesylate, venlafaxine, clonidine, etc.)

Product Name: Veozah

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., decrease in frequency and severity of vasomotor symptoms from baseline, etc.)

3 . References

1. Veozah Prescribing Information. Astellas Pharma US, Inc. Northbrook, IL. May 2023.

Verkazia (cyclosporine ophthalmic emulsion 0.1%) - PA, NF

Prior Authorization Guideline

Guideline Name	Verkazia (cyclosporine ophthalmic emulsion 0.1%) - PA, NF
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Verkazia (cyclosporine ophthalmic emulsion 0.1%)
Vernal Keratoconjunctivitis Indicated for the treatment of vernal keratoconjunctivitis in children and adults.

2 . Criteria

Product Name: Verkazia	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of	

clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia) [A, 1, 2, 3]

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following:

- Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine)
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn)

AND

3 - Trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone)

AND

4 - Prescribed by or in consultation with ONE of the following: [B ,3]

- Ophthalmologist
- Optometrist

Product Name: Verkazia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by an improvement in clinical signs and symptoms (e.g., itching, photophobia, papillary hypertrophy, mucus discharge, conjunctival hyperaemia)	

Product Name: Verkazia

Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe vernal keratoconjunctivitis confirmed by the presence of clinical signs and symptoms (e.g., itching, photophobia, giant papillae at the upper tarsal conjunctiva or at the limbus, thick mucus discharge, conjunctival hyperaemia) [A, 1, 2, 3]</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> • Topical ophthalmic “dual-acting” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine) • Topical ophthalmic mast cell stabilizers (e.g., cromolyn) <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) or paid claims confirming trial and failure, contraindication, or intolerance, for short term use (up to 2 to 3 weeks), of topical ophthalmic corticosteroids (e.g., dexamethasone, prednisolone, fluoromethalone)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with ONE of the following: [B ,3]</p> <ul style="list-style-type: none"> • Ophthalmologist • Optometrist 	

3 . Endnotes

- A. No precise diagnostic criteria have been established for this disease. Diagnosis is based on typical clinical signs and symptoms; thus, many mild or atypical cases may escape diagnosis. The lack of standardized diagnostic criteria and lack of common language

among physicians regarding the severity of VKC renders this disease more difficult to diagnose and treat. [2]

- B. A short-term, high-dose pulse regimen of topical corticosteroids is often necessary in patients with VKC who fail to respond to two to three weeks of a dual-acting antihistamine/mast cell stabilizer, particularly those with significant seasonal exacerbations. Close follow-up with an ophthalmologist is required due to vision-threatening side effects of topical corticosteroids, such as glaucoma, cataracts, and secondary infections. Patients should know that blindness is a risk of unsupervised topical corticosteroid therapy. [3]

4 . References

1. Verkazia prescribing information. Santen, Inc. Emeryville, CA. June 2021.
2. Kumar, S. Vernal keratoconjunctivitis: a major review. Available at <https://onlinelibrary.wiley.com/doi/10.1111/j.1755-3768.2008.01347.x>. Accessed April 5, 2022.
3. UpToDate. Vernal keratoconjunctivitis. Available at https://www.uptodate.com/contents/vernal-keratoconjunctivitis?search=VERNAL%20KERATOCONJUNCTIVITIS&source=search_result&selectedTitle=1~12&usage_type=default&display_rank=1#H18. Accessed April 5, 2022.

Verquvo (vericiguat)

Prior Authorization Guideline

Guideline Name	Verquvo (vericiguat)
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Verquvo (vericiguat)
Chronic Heart Failure Indicated to reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

2 . Criteria

Product Name: Verquvo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic heart failure	

AND

2 - Patient has an ejection fraction less than 45 percent

AND

3 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms

AND

4 - One of the following:

4.1 Patient was hospitalized for heart failure within the last 6 months

OR

4.2 Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months

AND

5 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [1-4]

5.1 One of the following:

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

5.2 One of the following: [A, 4]

- bisoprolol

- carvedilol
- metoprolol succinate extended-release

AND

5.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformn)]

AND

5.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

6 - Prescribed by or in consultation with a cardiologist

Product Name: Verquvo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

- A. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [4]

4 . References

1. Verquvo Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. June 2021.
2. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013 Oct 15;128(16):e240-327.
3. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *J Card Fail*. 2017 Aug;23(8):628-651.
4. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *Journal of Cardiac Failure*. Published online April 2022.

Prior Authorization Guideline

Guideline Name	Verzenio (abemaciclib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Verzenio (abemaciclib)
<p>Advanced or Metastatic Breast Cancer Indicated in combination with fulvestrant for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.</p> <p>Advanced or Metastatic Breast Cancer Indicated as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.</p> <p>Advanced or Metastatic Breast Cancer Indicated in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer.</p> <p>Early Breast Cancer Indicated in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.</p>

2 . Criteria

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Verzenio	
Diagnosis	Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

1. Verzenio Prescribing Information. Lilly USA, LLC. Indianapolis, IN. March 2023.

Viekira (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)

Prior Authorization Guideline

Guideline Name	Viekira (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
Chronic Hepatitis C Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV): a) genotype 1b without cirrhosis or with compensated cirrhosis, and b) genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin.

2 . Criteria

Product Name: Viekira Pak	
Diagnosis	Chronic Hepatitis C - Genotype 1a or Mixed Genotype 1 Infection – without Cirrhosis AND without Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection

AND

2 - Patient is without cirrhosis

AND

3 - Used in combination with ribavirin

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Patient has not experienced failure with a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (Daklinza [daclatasvir])

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, contraindication, or intolerance to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Viekira therapy

Product Name: Viekira Pak	
Diagnosis	Chronic Hepatitis C - Genotype 1a or Mixed Genotype 1 Infection – with Cirrhosis AND without Liver Transplant
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic hepatitis C genotype 1a or mixed genotype 1 infection	
AND	
2 - Patient has cirrhosis	

AND

3 - Used in combination with ribavirin

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious Disease Specialist
- HIV Specialist Certified through the Academy of HIV Medicine

AND

6 - Patient has not experienced failure with a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (Daklinza [daclatasvir])

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to **ONE** of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Viekira therapy

Product Name: Viekira Pak	
Diagnosis	Chronic Hepatitis C - Genotype 1b - without Liver Transplant
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 1b</p> <p style="text-align: center;">AND</p> <p>2 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hepatologist • Gastroenterologist • Infectious Disease Specialist • HIV Specialist Certified through the Academy of HIV Medicine 	

AND

4 - Patient has not experienced failure with a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (Daklinza [daclatasvir])

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]

AND

6 - One of the following:

6.1 Both of the following:

6.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

6.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

6.2 For continuation of prior Viekira therapy

Product Name: Viekira Pak	
Diagnosis	Chronic hepatitis C - Genotype 1 (Regardless of Subgenotype) – Liver Transplant Recipient
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Documentation that the patient is a liver transplant recipient

AND

3 - Patient has normal hepatic function and mild fibrosis (e.g., METAVIR fibrosis score less than or equal to F2)

AND

4 - Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Patient has not experienced failure with a previous treatment regimen that includes a HCV NS3/4A protease inhibitor [e.g., Incivek (telaprevir), Olysio (simeprevir), Victrelis (boceprevir)] or an NS5A inhibitor (Daklinza [daclatasvir])

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir)]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

- Brand Epclusa (sofosbuvir/velpatasvir)
- Brand Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Viekira therapy

3 . Background

Clinical Practice Guidelines			
Comparison of Scoring Systems for Histological Stage (Fibrosis)			
METAVIR	Batts-Ludwig	Knodell	Ishak
0	0	0	0
1	1	1	1
1	1	1	2
2	2	--	3
3	3	3	4

4	4	4	5
4	4	4	6

4 . References

1. Viekira Pak Prescribing Information. AbbVie, Inc. North Chicago, IL. December 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Prior Authorization Guideline

Guideline Name	Vijoice (alpelisib) - PA, NF
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Vijoice (alpelisib)
PIK3CA-Related Overgrowth Spectrum (PROS) Indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

2 . Criteria

Product Name: Vijoice	
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

AND

5 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., radiological response defined as a $\geq 20\%$ reduction from baseline in the sum of target lesion volume)	
AND	

2 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice

Approval Length	6 months [A]
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Therapy Stage	Initial Authorization
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of PIK3CA-Related Overgrowth Spectrum (PROS)

AND

2 - Submission of medical records (e.g., chart notes) confirming documentation of mutation in the PIK3CA gene

AND

3 - Patient is 2 years of age or older

AND

4 - Submission of medical records (e.g., chart notes) confirming documentation of severe clinical manifestations (e.g., Congenital Lipomatous Overgrowth, Vascular malformations, Epidermal nevi, Scoliosis/skeletal and spinal [CLOVES], Facial Infiltrating Lipomatosis [FIL], Klippel-Trenaunay Syndrome [KTS], Megalencephaly-Capillary Malformation Polymicrogyria [MCAP])

AND

5 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS

Product Name: Vijoice

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming documentation of positive clinical response to therapy (e.g., radiological response defined as a \geq 20% reduction from baseline in the sum of target lesion volume)</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a physician who specializes in the treatment of PROS</p>	

3 . Endnotes

- A. Patients without any response assessment at Week 24 were considered non-responders. [1]

4 . References

1. Vioice Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. April 2022.

Vitakvi (larotrectinib)

Prior Authorization Guideline

Guideline Name	Vitakvi (larotrectinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Vitakvi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.) with positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.) [1] AND 2 - Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution,	

TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations] [1]

AND

3 - Disease is one of the following:

- Metastatic
- Unresectable (including cases where surgical resection is likely to result in severe morbidity)

AND

4 - One of the following:

- Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy)
- Disease has no satisfactory alternative treatments

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Vitrakvi

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on Vitrakvi therapy

2 . References

1. Vitrakvi prescribing information. Loxo Oncology, Inc. Stamford, CT. November 2018.

Vivjoa (oteseconazole)

Prior Authorization Guideline

Guideline Name	Vivjoa (oteseconazole)
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Guideline Note:

Effective Date:	3/15/2023
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1 . Indications

Drug Name: Vivjoa (oteseconazole)
Recurrent Vulvovaginal Candidiasis Indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential.

2 . Criteria

Product Name: Vivjoa	
Approval Length	4 Month(s) [C]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of recurrent vulvovaginal candidiasis (RVVC)	

AND

2 - Patient is NOT of reproductive potential

AND

3 - Diagnosis of RVVC confirmed by one of the following [3]:

- Positive potassium hydroxide (KOH) preparation
- Vaginal fungal culture

AND

4 - Patient has experienced 3 or more symptomatic episodes of vulvovaginal candidiasis (VVC) within the past 12 months [A]

AND

5 - Trial and failure, contraindication, or intolerance to both of the following: [B]

- One intravaginal product (e.g., clotrimazole, miconazole, tioconazole, terconazole, boric acid)
- Oral fluconazole

3 . Endnotes

- A. Clinical trial inclusion criteria for Vivjoa included patients who had 3 or more episodes of acute vulvovaginitis in the past 12 months. Guidelines define RVVC as ≥ 3 or 4 symptomatic episodes of infection within 1 year. [1-4]
- B. For the treatment of recurring vulvovaginal candidiasis, 7 to 14 days of induction therapy with a topical agent or oral fluconazole, followed by oral fluconazole 150 mg weekly for 6 months is recommended. [2-4]
- C. Both dosage regimens require 12 weeks of Vivjoa, an additional 4 weeks is added to allow for any delays in obtaining oral fluconazole if needed. [1]

4 . References

1. Vivjoa Prescribing Information. Mycovia Pharmaceuticals. Durham, NC. April 2022.
2. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;62:e1-50.
3. Vulvovaginal Candidiasis - STI Treatment Guidelines. Cdc.gov. <https://www.cdc.gov/std/treatment-guidelines/candidiasis.htm>. Published 2021. Accessed August 3, 2022.
4. American College of Obstetricians and Gynecologists (ACOG). Vaginitis in nonpregnant patients: ACOG practice bulletin, number 215. *Obstet Gynecol*. 2020;135(1):e1-e17

Vizimpro (dacomitinib)

Prior Authorization Guideline

Guideline Name	Vizimpro (dacomitinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Vizimpro	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of non small cell lung cancer (NSCLC) [2] AND 2 - Disease is metastatic [2]	

AND

3 - Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: [2]

- Exon 19 deletion
- Exon 21 L858R substitution

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Vizimpro	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Vizimpro therapy	

2 . References

1. Vizimpro prescribing information. Pfizer Labs. New York, NY. September 2018.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-small cell lung cancer v.2.2019. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed December 1, 2018.

Vonjo (pacritinib)

Prior Authorization Guideline

Guideline Name	Vonjo (pacritinib)
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Guideline Note:

Effective Date:	11/1/2022
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1 . Indications

Drug Name: Vonjo (pacritinib)
Primary or Secondary Myelofibrosis Indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below $50 \times 10^9/L$.

2 . Criteria

Product Name: Vonjo	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of ONE of the following:[1]	

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

AND

2 - Disease is intermediate or high risk [1]

AND

3 - Pre-treatment platelet count below $50 \times 10^9/L$ [1]

AND

4 - Prescribed by or in consultation with **ONE** of the following:

- Hematologist
- Oncologist

Product Name: Vonjo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., symptom improvement, spleen volume reduction)</p>	

3 . Endnotes

- A. There is no "gold standard" for the diagnosis of PMF, although criteria have been proposed by the Italian Society of Hematology, the World Health Organization (WHO), and others [4]
- B. Secondary myelofibrosis refers to myelofibrosis that develops after polycythemia vera (PV) or essential thrombocythemia (ET). Our approach to evaluation and management of secondary myelofibrosis follows the suggestions for PMF [4]

4 . References

1. Vonjo Prescribing Information. CTI BioPharma Corp. Seattle, WA. February 2022.
2. The NCCN Clinical Practice Guidelines in Oncology - Myeloproliferative Neoplasms. Available at https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf . version 1.2022 - February 28, 2022. Accessed April 2, 2022.
3. UpToDate. Tefferi, A. Clinical manifestations and diagnosis of primary myelofibrosis. Available at [https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-primary-myelofibrosis?sectionName=Secondary%20myelofibrosis%20\(post-PV%20or%20post-ET\)&topicRef=4531&anchor=H2861686207&source=see_link#H2861686207](https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-primary-myelofibrosis?sectionName=Secondary%20myelofibrosis%20(post-PV%20or%20post-ET)&topicRef=4531&anchor=H2861686207&source=see_link#H2861686207) . Accessed April 2, 2022.
4. Leukemia and Lymphoma Society. Myelofibrosis. Available at <https://www.lls.org/myeloproliferative-neoplasms/myelofibrosis> . Accessed April 2, 2022.

Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin), Voquezna Dual Pak (vonoprazan, amoxicillin)

Prior Authorization Guideline

Guideline Name	Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin), Voquezna Dual Pak (vonoprazan, amoxicillin)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Voquezna Dual Pak (vonoprazan, amoxicillin)
Helicobacter pylori (H. pylori) Indicated for the treatment of Helicobacter pylori (H. pylori) in adults.
Drug Name: Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)
Helicobacter pylori (H. pylori) Indicated for the treatment of Helicobacter pylori (H. pylori) in adults.

2 . Criteria

Product Name: Voquezna Dual Pak, Voquezna Triple Pak	
Approval Length	1 month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of *Helicobacter pylori* infection

AND

2 - Trial and failure, contraindication, or intolerance to ONE of the following first line treatment regimens [B, C, 1, 3]

- Clarithromycin based therapy (e.g., clarithromycin based triple therapy, clarithromycin based concomitant therapy) [D]
- Bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor [PPI])

3 . Endnotes

- A. *H. pylori* is an infectious disease that is typically treated with combinations of 2–3 antibiotics along with a PPI, taken concomitantly or sequentially. Current guidelines recommend extended (10 to 14 days) treatment with all antibiotic regimens for *H. pylori*. [1]
- B. The American College of Gastroenterology, (ACG) treatment guideline for first-line and salvage therapies was last updated in 2017. The 2017 ACG guideline outlines evidence-based, frontline treatment strategies for providers in North America. These include clarithromycin triple therapy, bismuth quadruple therapy, concomitant therapy, sequential therapy, hybrid therapy, levofloxacin triple therapy. Due to the complexity of treatment, hybrid therapy as first line treatment is limited. Sequential therapy is also complex, and it is not uniformly endorsed as first line treatment. Due to the rising rates of levofloxacin resistance, levofloxacin should not be used for treatment, unless the *H. pylori* strain is known to be sensitive to it or if levofloxacin resistance rates are known to be less than 15 %. Studies evaluating the efficacy of levofloxacin containing regimens in North America are lacking. In clinical practice, the initial course of eradication therapy, heretofore referred to as “first-line” therapy, generally offers the greatest likelihood of treatment success. Thus, careful attention to the selection of the most appropriate first-line eradication therapy for an individual patient is essential. The ACG guidelines for the treatment of *H pylori* recommend several regimens for 1st line eradication therapy with no preference of 1 regimen over another. Therapy is individualized based on patient's previous antibiotic history and local resistance patterns. [1, 4]
- C. In the selection of the most appropriate empiric treatment regimen for *H pylori*, previous antibiotic exposure, regional antibiotic-resistance patterns, and eradication rates should be taken into consideration because these factors can impact successful treatment. Successful treatment also relies on host factors such as allergies and adherence. [3]

- D. Clarithromycin triple therapy consists of a PPI, clarithromycin, and amoxicillin or metronidazole. Clarithromycin based concomitant therapy consists of a PPI, amoxicillin, clarithromycin, and a nitroimidazole (e.g., tinidazole or metronidazole) [1, 4]

4 . References

1. Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori infection. Am J Gastroenterol. 2017; 112:212-238
2. Voquezna prescribing information. Phathom Pharmaceuticals, Inc. Buffalo Grove, IL. May 2022.
3. Myran, L., Zarbock, S. Management of Helicobacter pylori Infection. Available at <https://www.uspharmacist.com/article/management-of-helicobacter-pylori-infection>. Accessed June 14, 2022.
4. UptoDate. Treatment regimens for Helicobacter pylori in adults. April 7, 2022. Available at https://www.uptodate.com/contents/treatment-regimens-for-helicobacter-pylori-in-adults?search=h%20pylori%20infection&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed June 16, 2022.

Prior Authorization Guideline

Guideline Name	Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)
Chronic Hepatitis C (CHC) Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) who have: <ul style="list-style-type: none"> • Genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor. • Genotype 1a or 3 infection and have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. (Additional benefit of Vosevi over Eplclusa [sofosbuvir/velpatasvir] was not shown in adults with genotype 1b, 2, 4, 5, or 6 infection previously treated with sofosbuvir without an NS5A inhibitor.)

2 . Criteria

Product Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; without Decompensated Cirrhosis; Prior Relapser to NS5A-Based Regimen
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient is a previous relapser to an NS5A-based regimen (e.g., Daklinza [daclatasvir]; Epclusa [sofosbuvir/velpatasvir]; Harvoni [ledipasvir/sofosbuvir]; Mavyret [glecaprevir/pibrentasvir]; Technivie [ombitasvir/paritaprevir/ritonavir]; Viekira [ombitasvir/paritaprevir/ritonavir & dasabuvir]; Zepatier [elbasvir/grazoprevir])

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1a or 3; without Decompensated Cirrhosis; Prior Relapser to Sofosbuvir-Based Regimen without an NS5A Inhibitor
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a or 3

AND

2 - Patient is a previous relapser to a sofosbuvir-based regimen without an NS5A inhibitor

AND

3 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

4 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

Product Name: Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	
Diagnosis	Chronic Hepatitis C - Genotype 1, 2, 3, 4, 5, or 6; without Decompensated Cirrhosis; Prior Failure to Vosevi
Approval Length	24 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient had a prior treatment failure with Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

AND

3 - Used in combination with ribavirin

AND

4 - Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C)

AND

5 - Prescribed by or in consultation with one of the following:

- Hepatologist
- Gastroenterologist
- Infectious disease specialist
- HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir/sofosbuvir), Zepatier (elbasvir/grazoprevir)]

3 . References

1. Vosevi Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Votrient (pazopanib)

Prior Authorization Guideline

Guideline Name	Votrient (pazopanib)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Votrient (pazopanib)
Renal Cell Carcinoma (RCC) Indicated for the treatment of patients with advanced renal cell carcinoma (RCC).
Soft tissue sarcoma (STS) Indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. Limitation of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated.

2 . Criteria

Product Name: Votrient	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma

AND

2 - One of the following: [2]

- Disease has relapsed
- Diagnosis of stage IV disease

AND

3 - One of the following: [2]

3.1 One of the following:

3.1.1 Both of the following:

- Used in the treatment of non-clear cell renal cell carcinoma
- Trial and failure, contraindication or intolerance to generic sunitinib

OR

3.1.2 For continuation of prior therapy

OR

3.2 Patient has clear cell renal cell carcinoma

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Votrient

Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

Product Name: Votrient	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of advanced soft tissue sarcoma (STS) [4, A]</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist</p>	

Product Name: Votrient	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . Endnotes

- A. Votrient is an active drug in anthracycline pretreated STS patients with an increase in median PFS of 13 weeks. [3]

4 . References

1. Votrient Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. December 2021.
2. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Kidney cancer v.4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 28, 2023.
3. PALETTE: a randomized, double-blind, phase III trial of pazopanib versus placebo in patients (pts) with soft-tissue sarcoma (STS) whose disease has progressed during or following prior chemotherapy-An EORTC STBSG Global Network Study (EORTC 62072). Available at: www.asco.org/ascov2/Meetings/Abstracts?&vmview=abst_detail_view&confID=102&abstractID=83283. Accessed April 30, 2012.
4. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Soft tissue sarcoma v.2.2022. Available at: http://www.nccn.org/professionals/physician_gls/PDF/sarcoma.pdf. Accessed February 28, 2023.

Voxzogo (vosoritide)

Prior Authorization Guideline

Guideline Name	Voxzogo (vosoritide)
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Guideline Note:

Effective Date:	8/1/2022
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1 . Indications

Drug Name: Voxzogo (vosoritide)
Increase linear growth in pediatric patients with achondroplasia Indicated to increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

2 . Criteria

Product Name: Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Patient is 5 years of age or older

AND

2 - Patient has open epiphyses

AND

3 - Diagnosis of achondroplasia as confirmed by one of the following: [2, 3]

3.1 Both of the following:

3.1.1 Patient has clinical manifestations characteristic of achondroplasia (e.g., macrocephaly, frontal bossing, midface retrusion, disproportionate short stature with rhizomelic shortening of the arms and the legs, brachydactyly, trident configuration of the hands, thoracolumbar kyphosis, and accentuated lumbar lordosis)

AND

3.1.2 Patient has radiographic findings characteristic of achondroplasia (e.g., large calvaria and narrowing of the foramen magnum region, undertubulated, shortened long bones with metaphyseal abnormalities, narrowing of the interpedicular distance of the caudal spine, square ilia and horizontal acetabula, small sacrosiatic notches, proximal scooping of the femoral metaphyses, and short and narrow chest)

OR

3.2 Molecular genetic testing confirmed c.1138G>A or c.1138G>C variant (i.e., p.Gly380Arg mutation) in the fibroblast growth factor receptor-3 (FGFR3) gene

AND

4 - Patient did not have limb-lengthening surgery in the previous 18 months and does not plan on having limb-lengthening surgery while on Voxzogo therapy

AND

5 - Prescribed by or in consultation with one of the following:

- Clinical geneticist
- Endocrinologist
- A physician who has specialized expertise in the management of achondroplasia

Product Name: Voxzogo	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient continues to have open epiphyses</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of a positive clinical response to therapy as evidenced by one of the following:</p> <ul style="list-style-type: none">• Improvement in annualized growth velocity (AGV) compared to baseline• Improvement in height Z-score compared to baseline <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none">• Clinical geneticist• Endocrinologist• A physician who has specialized expertise in the management of achondroplasia	

3 . References

1. Voxzogo Prescribing Information. BioMarin Pharmaceutical Inc., Novato, CA. November 2021.

2. Pauli RM. Achondroplasia: a comprehensive clinical review. *Orphanet J Rare Dis* 2019;14(1):1-49.
3. Bacino CA. Achondroplasia. UpToDate. Available by subscription at: <http://www.uptodate.com/>. Accessed December 16, 2021.

Vtama (tapinarof)

Prior Authorization Guideline

Guideline Name	Vtama (tapinarof)
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Guideline Note:

Effective Date:	1/1/2023
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1 . Indications

Drug Name: Vtama (tapinarof) cream
Plaque Psoriasis (PsO) Indicated for the topical treatment of plaque psoriasis in adults.

2 . Criteria

Product Name: Vtama	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of plaque psoriasis	

AND

2 - Minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies [2]:

- Corticosteroids (e.g., betamethasone, clobetasol)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- Anthralin
- Coal tar

AND

3 - Prescribed by or in consultation with a dermatologist

Product Name: Vtama	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by one of the following [2]:	
<ul style="list-style-type: none">• Reduction in the body surface area (BSA) involvement from baseline• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	

3 . References

1. Vtama Prescribing Information. Dermavant Sciences Inc. Long Beach, CA. May 2022.
2. Elmetts CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. J Am Acad Dermatol 2021;84:432-70.

Prior Authorization Guideline

Guideline Name	Vuity (pilocarpine) - PA, NF
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Guideline Note:

Effective Date:	10/15/2022
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1 . Indications

Drug Name: Vuity (pilocarpine)
Presbyopia of the eye Indicated for the treatment of presbyopia in adults.

2 . Criteria

Product Name: Vuity	
Approval Length	1 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of presbyopia	

AND

2 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

AND

3 - Provider confirms valid clinical rationale, which excludes lifestyle choice, as to why patient is unable to use corrective lenses (e.g., eyeglasses or contact lenses)

Product Name: Vuity

Approval Length	6 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., improvement in near vision in low light conditions without lost of distance vision)

AND

2 - Prescribed by or in consultation with ONE of the following:

Ophthalmologist

Optometrist

Product Name: Vuity

Approval Length	1 month(s)
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Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of presbyopia</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with ONE of the following:</p> <ul style="list-style-type: none">OphthalmologistOptometrist <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) confirming patient is unable to use corrective lenses (e.g., eyeglasses or contact lenses)</p>	

3 . References

Vuity Prescribing Information. Abbvie Inc. North Chicago, IL. October 2021.

Wakix (pitolisant)

Prior Authorization Guideline

Guideline Name	Wakix (pitolisant)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Wakix (pitolisant)
Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1) Indicated for the treatment of cataplexy in adult patients with narcolepsy.
Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2) Indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy.

2 . Criteria

Product Name: Wakix	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of narcolepsy as confirmed by sleep study and submission of medical records documenting study results

AND

2 - Symptoms of cataplexy are present

AND

3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present

AND

4 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name: Wakix	
Diagnosis	Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy

AND

2 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Wakix	
Diagnosis	Narcolepsy without cataplexy (Narcolepsy Type 2)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study and submission of medical records documenting study results [A, B]</p> <p>AND</p> <p>2 - Symptoms of cataplexy are absent</p> <p>AND</p> <p>3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present</p> <p>AND</p> <p>4 - BOTH of the following:</p> <p>4.1 Trial and failure, contraindication, or intolerance to BOTH of the following:</p>	

Generic modafinil or armodafinil

Sunosi

AND

4.2 ONE of the following:

4.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

4.2.2 History of or potential for a substance use disorder

AND

5 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name: Wakix	
Diagnosis	Narcolepsy without cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy	

3 . Endnotes

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].

International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].

4 . References

Wakix Prescribing Information. Harmony Biosciences, LLC, Plymouth Meeting, PA. October 2020.

Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394.

UpToDate. Clinical features and diagnosis of narcolepsy in adults. Available by subscription at: https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=Clinical%20features%20and%20diagnosis%20of%20narcolepsy&source=search_result&selectedTitle=1~116&usage_type=default&display_rank=1. Accessed November 6, 2019.

Welireg (belzutifan)

Prior Authorization Guideline

Guideline Name	Welireg (belzutifan)
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Guideline Note:

Effective Date:	5/1/2022
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1 . Indications

Drug Name: Welireg (belzutifan)
Von Hippel-Lindau (VHL) disease Indicated for treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery

2 . Criteria

Product Name: Welireg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of von Hippel-Lindau (VHL) disease [A, 1]

AND

2 - Patient requires therapy for one of the following [A, 1] :

Renal cell carcinoma (RCC)

Central nervous system (CNS) hemangioblastoma

Pancreatic neuroendocrine tumor (pNET)

AND

3 - Patient does not require immediate surgery [A,1]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Welireg

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy [A, 1]

3 . Endnotes

The efficacy of WELIREG was evaluated in Study 004 (NCT03401788), an open-label clinical trial in 61 patients with VHL-associated RCC diagnosed based on a VHL germline alteration and with at least one measurable solid tumor localized to the kidney

as defined by response evaluation criteria in solid tumors (RECIST) v1.1. Enrolled patients had other VHL-associated tumors including CNS hemangioblastomas and pNET. CNS hemangioblastomas and pNET in these patients were diagnosed based on the presence of at least one measurable solid tumor in brain/spine or pancreas, respectively, as defined by RECIST v1.1 and identified by IRC. The study excluded patients with metastatic disease. Patients received WELIREG 120 mg once daily until progression of disease or unacceptable toxicity. The study population characteristics were: median age 41 years [range 19-66 years], 3.3% age 65 or older; 53% male; 90% were White, 3.3% were Black or African American, 1.6% were Asian, and 1.6% were Native Hawaiian or other Pacific Islander; 82% had an ECOG PS of 0, 16% had an ECOG PS of 1, and 1.6% had an ECOG PS of 2; and 84% had VHL Type I Disease. The median diameter of RCC target lesions per central independent review committee (IRC) was 2.2 cm (range 1-6.1). Median time from initial radiographic diagnosis of VHL-associated RCC tumors that led to enrollment on Study 004 to the time of treatment with WELIREG was 17.9 months (range 2.8-96.7). Seventy-seven percent of patients had prior surgical procedures for RCC. The major efficacy endpoint for the treatment of VHL-associated RCC was overall response rate (ORR) measured by radiology assessment using RECIST v1.1 as assessed by IRC. Additional efficacy endpoints included duration of response (DoR), and time to response (TTR).

4 . References

Welireg [Prescribing Information]. Merck & Co, Inc. Whitehouse Station, NJ. August 2021

Winlevi (clascoterone) cream

Prior Authorization Guideline

Guideline Name	Winlevi (clascoterone) cream
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Winlevi (clascoterone) cream
Acne Vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

2 . Criteria

Product Name: Winlevi	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acne vulgaris (i.e., acne)	

AND

2 - Patient is 12 years of age or older [a]

AND

3 - Trial and inadequate response (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to three of the following:

generic adapalene (cream, gel, lotion)

generic topical tretinoin or tretinoin microsphere

generic tazarotene cream

generic single-agent topical clindamycin product

generic dapsone gel

Product Name: Winlevi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

A subgroup analysis for subjects 9 to less than 12 years of age did not show a beneficial treatment effect, and the incidences of adverse events in this age group were higher compared to older adolescents and adults, including hypothalamic-pituitary-adrenal (HPA) suppression three-times that of the HPA suppression observed in adults. Also, this age group had a substantially higher incidence of hyperkalemia compared to other age

groups. These considerations led to the FDA approval of Winlevi in patients 12 years of age and older. [2]

4 . References

Winlevi Prescribing Information. Cassiopea, Inc. Milan, Italy. August 2020.

FDA Multi-Discipline Review. Available online at
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213433Orig1s000MultidisciplineR.pdf. Accessed January 4, 2021.

Xalkori (crizotinib)

Prior Authorization Guideline

Guideline Name	Xalkori (crizotinib)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Xalkori (crizotinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)- or ROS1-positive as detected by an FDA-approved test.
Anaplastic Large Cell Lymphoma (ALCL) Indicated for the treatment of pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. Limitations of use: The safety and efficacy of Xalkori have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.
Inflammatory Myofibroblastic Tumor Indicated for the treatment of adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor (IMT) that is ALK-positive.

2 . Criteria

Product Name: Xalkori

Diagnosis	Non-small Cell Lung Cancer (NSCLC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

2.1.2 One of the following:

2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

2.1.2.2 For continuation of prior therapy

OR

2.2 Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with

a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none">RelapsedRefractory <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <p style="padding-left: 40px;">Unresectable</p> <p style="padding-left: 40px;">Recurrent</p> <p style="padding-left: 40px;">Refractory</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

Product Name: Xalkori	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Xalkori Prescribing Information. Pfizer Labs. New York, NY. July 2022.

The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed August 12, 2022.

Xdemvy (lotilaner)

Prior Authorization Guideline

Guideline Name	Xdemvy (lotilaner)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Xdemvy (lotilaner ophthalmic solution)
Demodex Blepharitis Indicated for the treatment of Demodex blepharitis.

2 . Criteria

Product Name: Xdemvy	
Approval Length	2 months [A, 3]
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Demodex blepharitis	

AND

2 - Patient exhibits one of the following signs of Demodex infestation [2]

Collarettes [B, 2]

Eyelid margin erythema

Eyelash anomalies (e.g., eyelash misdirection)

AND

3 - Patient is experiencing symptoms or architectural changes associated with Demodex infestation (e.g., burning, tearing, itching, foreign body sensation, eyelashes missing, eyelashes growing inward) [C, 3]

AND

4 - Trial and inadequate response to tea tree-oil [D-E, 3-4]

AND

5 - Prescribed by or in consultation with one of the following:

Ophthalmologist

Optometrist

3 . Definitions

Definition	Description
Collarettes	Solidified exudative excretions that form a cylindrical collar around the base of the eyelash follicle - are the pathognomonic sign of Demodex blepharitis [2].

4 . Endnotes

Xdemvy kills the "adult" mite. However, the product does not kill the eggs. The life cycle of the mite is about 27 days. The eggs will hatch. If stop prior to this, those 2nd generation mites won't be killed. Need 2 or 3 generations to eradicate mites and eggs that will hatch. Multiple courses of treatment may be necessary. The physician would re-evaluate patient after 3 months not 6 weeks. Goal of treatment is to get to a threshold below where the patient is not experiencing symptoms. Mites live on clothes, pillowcases, sheets so re-infection possible. For this reason, difficult to eradicate to where there are "zero" mites.[3]

Collarettes are often referred to in the literature as cylindrical dandruff (CD), sleeves, cuffs, crusting, or lash debris [2]

If Demodex is not overpopulated and not causing problem can leave it alone; if burning, tearing, itching, foreign body sensation, etc. or architectural changes in lid, eyelashes missing, eyelashes grow inward (scratching cornea, scarring), consider treating the Demodex blepharitis [3]

Tea Tree Oil has been the standard treatment. It suppresses the mite and tricks the mite into coming out of its buried status in the skin. Mites are nocturnal, so they are embedded during the day and come out at night. Tea tree oil is available in shampoos, soaps, and specific ocular products (e.g., Cliradex 10% wipes or foam) and are available OTC. Cliradex 50% is available and is used as an in office procedure since higher concentrations can be very irritating to the eyes and skin [3]

In general, topical formulations containing tea tree oil were reported to be effective in reducing the number of Demodex mites on eyelashes. Other emerging treatment options include anti-parasitic drugs and IPL, but there is currently limited high-quality evidence to ascertain the efficacy of these treatments for ocular Demodex with any certainty. [4]

5 . References

Xdemvy Prescribing Information. Tarsus Pharmaceuticals, Inc. Irvine, CA. July 2023.

Rhee, M., Yeu, E., Barnett., M., et al. Demodex Blepharitis: A Comprehensive Review of the Disease, Current Management, and Emerging Therapies. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10351901/>. Accessed October 26, 2023.

Clinical Consult with Ophthalmologist. September 13, 2023.

Zhang, A., Muntz, A., Wang, M., et al. Ocular Demodex: A systematic review of the clinical literature. Avaialbe at:

file:///C:/Users/kdekhtaw/Downloads/Zhang%20et%20al%202020_SR%20(1).pdf.
Accessed October 26, 2023.

ClinicalTrials.gov. Safety and Efficacy of TP-03 for the Treatment of Demodex Blepharitis (Saturn-1). Available at:
<https://www.clinicaltrials.gov/study/NCT04784091?cond=demodex%20blepharitis&rank=4>. Accessed October 26, 2023.

ClinicalTrials.gov. Trial to Evaluate the Safety and Efficacy of TP-03 for the Treatment of Demodex Blepharitis (Saturn-2). Available at:
<https://www.clinicaltrials.gov/study/NCT04784091?cond=demodex%20blepharitis&rank=4>. Accessed October 26, 2023.

Prior Authorization Guideline

Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Xeljanz (tofacitinib) tablets, Xeljanz XR (tofacitinib) extended-release tablets

Rheumatoid Arthritis (RA) Indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ankylosing Spondylitis (AS) Indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Ulcerative Colitis (UC) Indicated for the treatment of adult patients with moderately to severely active ulcerative colitis, who have an inadequate response or intolerance to one or more TNF blockers. Limitations of Use: Use of Xeljanz/Xeljanz XR in combination with

biological therapies for UC or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Drug Name: Xeljanz (tofacitinib) tablets and oral solution

Polyarticular Course Juvenile Idiopathic Arthritis Indicated for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers.
Limitations of Use: Use of Xeljanz in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

2 . Criteria

Product Name: Xeljanz tablets or Xeljanz XR tablets

Diagnosis	Rheumatoid Arthritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderately to severely active rheumatoid arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [2, 3]:

methotrexate

leflunomide

sulfasalazine

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets

Diagnosis Rheumatoid Arthritis

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1-3]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Xeljanz tablets and oral solution	
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Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
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Approval Length	6 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of active polyarticular course juvenile idiopathic arthritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses [4]:

leflunomide

methotrexate

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, etanercept)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets and oral solution

Diagnosis Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 4]:

Reduction in the total active (swollen and tender) joint count from baseline

Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets

Diagnosis Psoriatic Arthritis

Approval Length 6 month(s)

Therapy Stage Initial Authorization

Guideline Type Prior Authorization

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [5]:

Actively inflamed joints

Dactylitis

Enthesitis

Axial disease

Active skin and/or nail involvement

AND

3 - Prescribed by or in consultation with one of the following:

Dermatologist

Rheumatologist

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).
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Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic Arthritis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5]:</p> <ul style="list-style-type: none"> Reduction in the total active (swollen and tender) joint count from baseline Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline Reduction in the body surface area (BSA) involvement from baseline <p style="text-align: center;">AND</p> <p>2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*</p>	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active ankylosing spondylitis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Minimum duration of one month trial and failure, contraindication, or intolerance to two different NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [6]

AND

4 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol, etanercept, golimumab)

AND

5 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets

Diagnosis Ankylosing Spondylitis (AS)

Approval Length 12 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 6]:

Disease activity (e.g., pain, fatigue, inflammation, stiffness)

Lab values (erythrocyte sedimentation rate, C-reactive protein level)

Function

Axial status (e.g., lumbar spine motion, chest expansion)

Total active (swollen and tender) joint count

AND

2 - Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	4 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of moderately to severely active ulcerative colitis	
AND	
2 - One of the following [7, 8]:	
Greater than 6 stools per day	

Frequent blood in the stools

Frequent urgency

Presence of ulcers

Abnormal lab values (e.g., hemoglobin, ESR, CRP)

Dependent on, or refractory to, corticosteroids

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [7, 8]:

6-mercaptopurine

Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)

Azathioprine

Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, golimumab)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*

Notes

*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:</p> <p style="padding-left: 40px;">Improvement in intestinal inflammation (e.g., mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline</p> <p style="padding-left: 40px;">Reversal of high fecal output state</p> <p style="text-align: center;">AND</p> <p>2 - Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*</p>	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topical or inhaled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

Initial approval length of 4 months based on dosing recommendation provided in the labeling of Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily for at least 8 weeks, followed by Xeljanz 5 mg once or twice daily, 10 mg twice daily, or Xeljanz XR 11 mg once daily depending on therapeutic response. Xeljanz should be discontinued after 16 weeks (4 months) of treatment with Xeljanz 10 mg twice daily or Xeljanz XR 22 mg once daily if adequate therapeutic response is not achieved.

4 . References

Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. January 2022.

- Singh JA, Saag KG, Bridges SL Jr, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Care Res.* 2015;68(1):1-25.
- Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. 2021;73(7):924-939.
- Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Rheumatol.* 2019;71(6):846-863.
- Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.
- Ward MM, Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/spondyloarthritis research and treatment network recommendations for the treatment of ankylosing spondylitis and nonradiographic axial spondyloarthritis. *Arthritis Rheumatol.* 2019;71(10):1599-1613.
- Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol* 2019;114:384–413.
- Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterol.* 2020;158:1450-1461.

Xeloda (capecitabine)

Prior Authorization Guideline

Guideline Name	Xeloda (capecitabine)
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Guideline Note:

Effective Date:	9/1/2023
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1 . Indications

Drug Name: Xeloda (capecitabine)
<p>Colorectal Cancer Indicated for (1) for the adjuvant treatment of patients with Stage III colon cancer as a single agent or as a component of a combination chemotherapy regimen; 2) the perioperative treatment of adults with locally advanced rectal cancer as a component of chemoradiotherapy; 3) Indicated for the treatment of patients with unresectable or metastatic colorectal cancer as a single agent or as a component of a combination chemotherapy regimen.</p>
<p>Breast Cancer Indicated for 1) the treatment of patients with advanced or metastatic breast cancer as a single agent if an anthracycline- or taxane-containing chemotherapy is not indicated; 2) the treatment of patients with advanced or metastatic breast cancer in combination with docetaxel after disease progression on prior anthracycline-containing chemotherapy.</p>
<p>Gastric, Esophageal, or Gastroesophageal Junction Cancer Indicated for the 1) treatment of adults with unresectable or metastatic gastric, esophageal, or gastroesophageal junction cancer as a component of a combination chemotherapy regimen; 2) treatment of adults with HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma who have not received prior treatment for metastatic disease as a component of a combination regimen.</p>
<p>Pancreatic Cancer Indicated for the adjuvant treatment of adults with pancreatic adenocarcinoma as a component of a combination chemotherapy regimen.</p>

2 . Criteria

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Colorectal Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of colorectal cancer</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <p style="padding-left: 40px;">Stage III or Locally Advanced</p> <p style="padding-left: 40px;">Unresectable</p> <p style="padding-left: 40px;">Metastatic</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with an oncologist</p> <p style="text-align: center;">AND</p> <p>4 - Both of the following (applies to BRAND Xeloda only):</p> <p style="padding-left: 20px;">4.1 Trial and failure or intolerance to generic capecitabine</p>	

AND

4.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Xeloda, generic capecitabine

Diagnosis	Breast Cancer
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Approval Length	12 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of breast cancer

AND

2 - Disease is one of the following:

Advanced

Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - Both of the following (applies to BRAND Xeloda only):

4.1 Trial and failure or intolerance to generic capecitabine

AND

4.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Gastric, Esophageal, or Gastroesophageal Junction Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of one of the following:	
Gastric Cancer	
Esophageal Cancer	
Gastroesophageal Junction Cancer	
AND	

2 - Disease is one of the following:

Unresectable

Metastatic

AND

3 - Prescribed by or in consultation with an oncologist

AND

4 - Both of the following (applies to BRAND Xeloda only):

4.1 Trial and failure or intolerance to generic capecitabine

AND

4.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Pancreatic Cancer

AND

2 - Prescribed by or in consultation with an oncologist

AND

3 - Both of the following (applies to BRAND Xeloda only):

3.1 Trial and failure or intolerance to generic capecitabine

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Brand Xeloda, generic capecitabine	
Diagnosis	All Indications Listed Above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

AND

2 - Both of the following (applies to BRAND Xeloda only):

2.1 Trial and failure or intolerance to generic capecitabine

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . References

Xeloda prescribing information. Genentech, Inc. South San Francisco, CA. December 2022.

Xenazine (tetrabenazine)

Prior Authorization Guideline

Guideline Name	Xenazine (tetrabenazine)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Xenazine (tetrabenazine)
Chorea associated with Huntington's disease Indicated for the treatment of chorea associated with Huntington's disease.
Off Label Uses: Hyperkinetic movement disorders in tardive dyskinesia and Tourette's syndrome [2-5] Has shown effectiveness in the treatment of hyperkinetic movement disorders (hyperkinesias) characterized by abnormal involuntary movements seen in tardive dyskinesia (TD), or issues such as tics (eye blink, shouting obscenities or profanities, etc.) observed in Tourette's syndrome (TS).

2 . Criteria

Product Name: Brand Xenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chorea in patients with Huntington's disease

AND

2 - Prescribed by or in consultation with a neurologist [C]

AND

3 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chorea in patients with Huntington's disease	
AND	
2 - Prescribed by or in consultation with a neurologist [C]	

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Chorea associated with Huntington's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

Product Name: Brand Xenazine

Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has tics associated with Tourette's syndrome [2, 4]

AND

2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine

Diagnosis	Tourette's syndrome (Off-label)
Approval Length	3 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has tics associated with Tourette's syndrome [2, 4]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to a minimum 30 day supply of Haldol (haloperidol)</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <p style="padding-left: 40px;">Neurologist</p> <p style="padding-left: 40px;">Psychiatrist</p>	

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

Product Name: Brand Xenazine

Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of tardive dyskinesia [3, 4]

AND

2 - One of the following [A, 5]:

2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication

AND

3 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

AND

4 - Trial and failure or intolerance to a minimum 30 day supply of generic tetrabenazine

Product Name: Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)

Approval Length	3 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of tardive dyskinesia [3, 4]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following [A, 5]:</p> <p style="padding-left: 20px;">2.1 Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Patient is not a candidate for a trial of dose reduction, tapering or discontinuation of the offending medication</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <p style="padding-left: 40px;">Neurologist</p> <p style="padding-left: 40px;">Psychiatrist</p>	

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tardive dyskinesia (Off-label)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy

3 . Endnotes

Verified with consultant for a previous medication (Ingrezza [valbenazine]) that dose reduction, tapering, or discontinuation of the offending medication is considered first-line treatment for tardive dyskinesia. [5]

Authorization period is based on the pivotal study duration of 12 weeks. [1]

Ensures the requirement for proper diagnosing and quantifying an adequate chorea score (total maximal chorea score of greater than or equal to 10 (moderate to severe chorea) from the subscale of the Unified Huntington's Disease Rating Scale (UHDRS). Note that the pivotal trial that established efficacy of tetrabenazine included patients with a total maximal chorea of greater than or equal to 10. [1]

4 . References

Xenazine Prescribing Information. Lundbeck. Deerfield, IL. November 2019.

Sweet RD, Braun R, Shapiro E, Shapiro AK. Presynaptic catecholamine antagonists as treatment for Tourette syndrome. Effects of alpha methyl para tyrosine and tetrabenazine. Arch Gen Psych. 1974;31:857-861.

Kazamatsuri H, Chien C-P, Cole J. Treatment of Tardive Dyskinesia: clinical efficacy of a dopamine-depleting agent, tetrabenazine. Arch Gen Psychiat. 1972;27:95-99.

Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at: <https://www.micromedexsolutions.com>. Accessed April 1, 2021.

Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

Xenpozyme (olipudase alfa)

Prior Authorization Guideline

Guideline Name	Xenpozyme (olipudase alfa)
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Guideline Note:

Effective Date:	4/15/2023
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1 . Indications

Drug Name: Xenpozyme (olipudase alfa)
Acid Sphingomyelinase Deficiency (ASMD) Indicated for treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients.

2 . Criteria

Product Name: Xenpozyme	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acid sphingomyelinase deficiency (ASMD)*	

AND

2 - Disease confirmed by ONE of the following: [2]

2.1 Molecular genetic testing confirms biallelic pathogenic variants in the SMPD1 (sphingomyelin phosphodiesterase-1) gene

OR

2.2 Residual acid sphingomyelinase activity that is less than 10% of controls (in peripheral blood lymphocytes or cultured skin fibroblasts)

AND

3 - Submission of medical records (e.g., chart notes) documenting patient has non-central nervous system manifestations of ASMD

AND

4 - Prescribed by or in consultation with ONE of the following:

Metabolic disease specialist

Geneticist

Notes

*Acid Sphingomyelinase Deficiency is also known as Niemann-Pick Disease types A, A/B, and B [1]

Product Name: Xenpozyme

Approval Length 24 month(s)

Therapy Stage Reauthorization

Guideline Type Prior Authorization

Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy (e.g., decrease in spleen size, decrease in liver size, increase in platelet count, improved lung function)

3 . References

Healthcare professional brochure. Available at www.xenpozyme.com/pdfs/v0.0.1/hcp/hcp-brochure.pdf. Accessed October 4, 2022.

Wasserstein, M., Schuchman, E., et al. Acid Sphingomyelinase Deficiency. Available at <https://pubmed.ncbi.nlm.nih.gov/20301544/>. Accessed October 4, 2022.

McGovern, M., Dionisi-Vici, C., et al. Consensus recommendation for a diagnostic guideline for acid sphingomyelinase deficiency. Available at <https://pubmed.ncbi.nlm.nih.gov/28406489/>. Accessed October 4, 2022.

Living with ASMD. Available at Proactive Symptom Management While Living with ASMD (asmdfacts.com). Accessed October 4, 2022.

Xenpozyme prescribing information. Cambridge, MA. Genzyme Corporation. August 2022.

Prior Authorization Guideline

Guideline Name	Xeomin (incobotulinumtoxinA)
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Guideline Note:

Effective Date:	2/15/2024
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1 . Indications

Drug Name: Xeomin (incobotulinumtoxinA)
Blepharospasm Indicated for the treatment of blepharospasm in adults.
Cervical Dystonia Indicated for the treatment of cervical dystonia in adults.
Chronic Sialorrhea Indicated for the treatment of chronic sialorrhea in patients 2 years of age and older.
Adult Upper Limb Spasticity Indicated for the treatment of upper limb spasticity in adults.
Pediatric Upper Limb Spasticity Indicated for the treatment of upper limb spasticity in pediatric patients 2 to 17 years of age, excluding spasticity caused by cerebral palsy.
Glabellar Lines* Is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults. *Note: Use of Xeomin for the improvement in the appearance of glabellar lines is excluded, as this is considered a cosmetic use.

2 . Criteria

Product Name: Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of cervical dystonia (also known as spasmodic torticollis) [1]</p>	

Product Name: Xeomin	
Diagnosis	Cervical Dystonia (also known as spasmodic torticollis)
Approval Length	3 months [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have elapsed or will have elapsed since the last treatment [1]</p>	

Product Name: Xeomin	
Diagnosis	Blepharospasm
Approval Length	3 months [1, B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of blepharospasm

Product Name: Xeomin

Diagnosis	Blepharospasm
Approval Length	3 months [1, 4, C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 3 months have elapsed or will have elapsed since the last treatment [C]

Product Name: Xeomin

Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of upper limb spasticity [1]

AND

2 - Patient is 2 years of age or older

Product Name: Xeomin

Diagnosis	Upper Limb Spasticity
Approval Length	3 months [1, 3, D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have elapsed or will have elapsed since the last treatment [D]</p>	

Product Name: Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic sialorrhea</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age or older</p>	

Product Name: Xeomin	
Diagnosis	Chronic Sialorrhea
Approval Length	3 months [1, D]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - At least 4 months have elapsed or will have elapsed since the last treatment [E]

3 . Endnotes

In a randomized, double-blind, active-controlled, parallel group study, 463 patients with a documented stable therapeutic response to Botox as a result of the last two consecutive injection sessions directly prior to trial entry (70 to 300 Units) were included. Patients in the study received IM injections of 70 to 300 Units of Xeomin or Botox, based on the previous two consecutive doses of Botox prior to study entry. [2]

The total initial dose of Xeomin in both eyes should not exceed 50 Units (25 Units/eye). [1]

The median onset of treatment effect with incobotulinumtoxinA was 4 days (range, 0 to 30 days), time to waning of treatment effect was 6 weeks (range 1 to 15 weeks), and duration of treatment effect was 10.6 weeks (range, 6.1 to 19.1 weeks). [4]

The typical duration of effect of each treatment is up to 12-16 weeks; however, the duration of effect may vary in individual patients. [1]

The timing for repeat treatment of chronic sialorrhea should be determined based on the actual clinical need of the individual patient, and no sooner than every 16 weeks (4 months). [1]

4 . References

Xeomin Prescribing Information. Merz Pharmaceuticals, LLC. Raleigh, NC. August 2021.

Benecke R, Jost WH, Kanovsky P, Ruzicka E, Comes G, Grafe S. A new botulinum toxin type A free of complexing proteins for treatment of cervical dystonia. *Neurology*. 2005;64:1949-1951.

Kanovsky P, Slawek J, Denes Z, et al. Efficacy and safety of treatment with incobotulinum toxin A (botulinum neurotoxin type A free from complexing proteins; NT 201) in post-stroke upper limb spasticity. *J Rehabil Med* 2011; 43(6):486-492.

Jankovic J, Comella C, Hanschmann A, et al. Efficacy and safety of incobotulinumtoxinA (NT 201, Xeomin) in the treatment of blepharospasm-a randomized trial. *Mov Disord* 2011; 26(8):1521-1528.

Xermelo (telotristat ethyl)

Prior Authorization Guideline

Guideline Name	Xermelo (telotristat ethyl)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Xermelo*	
Approval Length	6 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of carcinoid syndrome diarrhea AND 2 - Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months [1-5]	

AND	
3 - Used in combination with SSA therapy	
AND	
4 - Prescribed by or in consultation with one of the following:	
Oncologist	
Endocrinologist	
Gastroenterologist	
Notes	*Prior authorization may not apply depending on the plan.

Product Name: Xermelo*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of a positive clinical response to Xermelo therapy	
AND	
2 - Xermelo will continue to be used in combination with SSA therapy	
Notes	*Prior authorization may not apply depending on the plan.

2 . Endnotes

In an open label extension of the TELESTAR trial, bowel movement (BM) reductions were consistent with the results from the double-blind trial period [5].

3 . References

Xermelo Prescribing Information. Lexicon Pharmaceuticals, Inc. The Woodlands, TX. February 2017.

Eriksson B, Klöppel G, Krenning E, et al. Consensus guidelines for the management of patients with digestive neuroendocrine tumors – well-differentiated jejunal-ileal tumor/carcinoma. *Neuroendocrinology* 2008;87:8-19.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Neuroendocrine and Adrenal Tumors v.2.2018. Available by subscription at: https://www.nccn.org/professionals/physician_gls/PDF/neuroendocrine.pdf. Accessed August 15, 2018.

Kulke MH, Anthony LB, Bushnell DL, et al. NANETS Treatment Guidelines: Well differentiated neuroendocrine tumors of the stomach and pancreas. *Pancreas*. 2010 Aug; 39(6): 735–752. doi: 10.1097/MPA.0b013e3181ebb168.

Kulke MH, Horsch D, Caplin ME, et al. Telotristat ethyl, a tryptophan hydroxylase inhibitor for the treatment of carcinoid syndrome. *J Clin Oncol*. 2017 Jan;35(1):14-23. Epub 2016 Oct 28.

Xiaflex (collagenase clostridium histolyticum)

Prior Authorization Guideline

Guideline Name	Xiaflex (collagenase clostridium histolyticum)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Xiaflex	
Diagnosis	Dupuytren's contracture
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of Dupuytren's contracture with a palpable cord AND 2 - Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) [A]	

AND

3 - Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint [B]

AND

4 - Patient has a flexion deformity that results in functional limitations

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Peyronie's disease	
AND	
2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy [C]	
AND	
3 - The plaques do not involve the penile urethra	
AND	
4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse) [C]	

Product Name: Xiaflex	
Diagnosis	Peyronie's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Peyronie's disease</p> <p style="text-align: center;">AND</p> <p>2 - Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy</p> <p style="text-align: center;">AND</p> <p>3 - The plaques do not involve the penile urethra</p> <p style="text-align: center;">AND</p> <p>4 - Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)</p> <p style="text-align: center;">AND</p> <p>5 - Patient has a new plaque that results in a curvature deformity</p>	

2 . Endnotes

Dupuytren's disease diagnosis can include a table top test to assess the severity of the disease. When a patient is unable to place his or her palm and the affected finger flat on the table, the test can help diagnosis Dupuytren's disease. [1]

Dupuytren's disease is associated with joint contracture. Xiaflex was studied in a patient population with joint contracture of at least 20 degrees. Evidence does not support any benefit in patients with joint contracture less than 20 degrees. Our program requires that the patient has a flexion deformity that results in functional limitations to protect against cosmetic use. [1]

Peyronie's disease is characterized by a curvature deformity. Xiaflex was studied in a patient population with a curvature deformity of at least 30 degrees. Evidence does not support any benefit in patients with a curvature deformity less than 30 degrees. To prevent cosmetic use, patients must also have a curvature deformity that results in pain. [1]

3 . References

Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. June 2018.

Prior Authorization Guideline

Guideline Name	Xifaxan (rifaximin) - PA, NF
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Xifaxan (rifaximin)

Travelers' Diarrhea 200mg is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older. Limitations of use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. [A]

Prophylaxis of Hepatic Encephalopathy Recurrence 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. In the trials of Xifaxan for HE, 91% of patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) score greater than 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction.

Irritable Bowel Syndrome with Diarrhea 550 mg is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Off Label Uses: Treatment of Hepatic Encephalopathy Used for the treatment of hepatic encephalopathy. [4, 5, 22]

Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) Has been used for the treatment of small intestinal bacterial overgrowth. [7, 8, 10, 13]

2 . Criteria

Product Name: Xifaxan 200 mg tablets	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of travelers' diarrhea (TD)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is moderate to severe [D, 9]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Trial and failure of one of the following: [2, 3, D, E]</p> <p>Zithromax (azithromycin)</p> <p>Cipro (ciprofloxacin)</p> <p>Levaquin (levofloxacin)</p> <p>Ofloxacin</p> <p style="text-align: center;">OR</p> <p>3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:</p> <p>Zithromax (azithromycin)</p>	

Cipro (ciprofloxacin)
Levaquin (levofloxacin)
Ofloxacin

Product Name: Xifaxan 200 mg tablets

Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of travelers' diarrhea (TD)

AND

2 - Disease is moderate to severe [D, 9]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting one of the following:

3.1 Trial and failure of one of the following: [2, 3, D, E]

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

OR

3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Zithromax (azithromycin)

Cipro (ciprofloxacin)

Levaquin (levofloxacin)

Ofloxacin

Product Name: Xifaxan

Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)

AND

2 - One of the following:

2.1 Trial and failure of two of the following antibiotics: [5, 16-21]

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

OR

2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:

Neomycin

Augmentin (amoxicillin/clavulanic acid)

Cipro (ciprofloxacin)

Bactrim (trimethoprim-sulfamethoxazole)

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline

Flagyl (metronidazole)

Keflex (cephalexin)

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., resolution of symptoms or relapse with Xifaxan discontinuation) [B]	

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)

Approval Length	3 Months [C]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) documenting one of the following:</p> <p>2.1 Trial and failure of two of the following antibiotics: [5, 16-21]</p> <p>Neomycin</p> <p>Augmentin (amoxicillin/clavulanic acid)</p> <p>Cipro (ciprofloxacin)</p> <p>Bactrim (trimethoprim-sulfamethoxazole)</p> <p>Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline</p> <p>Flagyl (metronidazole)</p> <p>Keflex (cephalexin)</p> <p style="text-align: center;">OR</p> <p>2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:</p> <p>Neomycin</p> <p>Augmentin (amoxicillin/clavulanic acid)</p> <p>Cipro (ciprofloxacin)</p> <p>Bactrim (trimethoprim-sulfamethoxazole)</p>	

Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline
Flagyl (metronidazole)
Keflex (cephalexin)

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) [F]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older [L]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to both of the following:</p> <p style="padding-left: 40px;">Tricyclic antidepressant (amitriptyline)</p> <p style="padding-left: 40px;">Viberzi</p>	

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Symptoms of Irritable Bowel Syndrome continue to persist [G, H]

AND

2 - Documentation of positive clinical response to therapy as evidenced by both of the following: [1]

Improvement in abdominal pain

Reduction in the Bristol Stool Scale

AND

3 - Trial and failure, contraindication, or intolerance to both of the following:

Tricyclic antidepressant (amitriptyline)

Viberzi

Product Name: Xifaxan 550 mg tablets	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence	
AND	

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [J, 22]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Product Name: Xifaxan 550 mg tablets

Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy [M, 27, 28]

Product Name: Xifaxan

Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [22, K]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Product Name: Xifaxan	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	
1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]	

AND

2 - Patient is 18 years of age or older [L]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting one of the following: [22, K]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

3 . Endnotes

Antibiotic treatment should be avoided in diarrhea caused by enterohemorrhagic E. coli. [6]

The main goals in the treatment of SBBO are 1) treatment of underlying small intestinal abnormality, when possible; 2) concentration on long-term antibiotic therapy when surgical management is not feasible; 3) adjunctive treatment of dysmotility, such as a prokinetic agent; and 4) nutritional support, particularly in patients with weight loss or vitamin deficiency. [7]

In most patients, a single course of treatment (10 days) markedly improves symptoms, and patients may remain free of symptoms for months. In others, symptoms recur quickly, and acceptable results can only be obtained with cyclic treatment (1 of every 4 weeks). In still others, continuous treatment may be needed for 1 to 2 months. If the antimicrobial agent is effective, a resolution or marked diminution of symptoms will be notable within several days of initiating therapy. Diarrhea and steatorrhea will decrease, and cobalamin malabsorption will be corrected. [7]

According to the Centers for Disease Control and Prevention's Yellow Book, antibiotics may be used to treat cases of moderate to severe travelers' diarrhea. Fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of Traveler's Diarrhea (TD). Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. The overall usefulness of Rifaximin for empiric self-treatment remains to be determined as Rifaximin has only been shown to be efficacious in patients with noninvasive strains of *E. coli*. [9]

Levofloxacin, ofloxacin and ciprofloxacin have all been shown to be highly effective in the treatment and prevention of Travelers' Diarrhea and should be considered first-line therapy options for this indication. [11]

In the TARGET I, II and III pivotal trials, Irritable Bowel Syndrome was diagnosed using the ROME II diagnostic criteria. According to the ROME-II criteria, an IBS-D diagnosis requires at least 12 consecutive weeks in the previous 12 months of abdominal discomfort or pain that has two out of the three following features: relieved with defecation; and/or onset associated with a change in frequency of stool; and/or onset associated with a change in appearance of stool [12, 14]

In the TARGET III pivotal trial, a total of 636 responders (59%) required retreatment. The median time to recurrence for patients who experienced initial response was 10 weeks (range from 6 to 24 weeks) [14]

According to the ROME-IV criteria, recurrent signs and symptoms of IBS-D include the following: a return of abdominal pain or mushy/watery stool consistency for at least 3 weeks during a 4-week follow-up period. [15]

The recommended dose of Xifaxan for IBS-D is one 550 mg tablet taken orally three times a day for 14 days. [1]

The American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) recommend rifaximin as an effective add-on therapy to lactulose for prevention of over hepatic encephalopathy with strength of recommendation 1A. No solid data support the use of rifaximin alone. [22]

Rifaximin has been used for the treatment of HE in a number of trials comparing it with placebo, other antibiotics, nonabsorbable disaccharides, and in dose-ranging studies. These trials showed effect of rifaximin that was equivalent or superior to the compared agents with good tolerability. No solid data support the use of rifaximin alone. [22]

A minimum age requirement that aligns with the prescribing information was added for prophylaxis and treatment of hepatic encephalopathy and IBS-D to prevent misuse of Xifaxan in pediatrics. The same age requirement was not added for traveler's diarrhea or SBBO/SIBO due to the patient population (e.g., pediatrics) that Xifaxan was studied in. [1, 8, 10, 13, 26]

The risk of a breakthrough episode of hepatic encephalopathy (HE) in patients who recently had history of recurrent overt HE was reduced while taking Xifaxan. Additionally, patients

on Xifaxan achieved full resolution of HE, so there is benefit with long-term use of Xifaxan for the prophylaxis of HE. [27, 28]

4 . References

- Xifaxan prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. October 2020.
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Xiidra (lifitegrast)

Prior Authorization Guideline

Guideline Name	Xiidra (lifitegrast)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Xiidra (lifitegrast)
Dry eye disease Indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2 . Criteria

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of dry eye disease	

Product Name: Xiidra	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)</p>	

3 . Endnotes

As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

Xiidra Prescribing Information. Shire US Inc. Lexington, MA. March 2020.

American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018.
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Xolair (omalizumab)

Prior Authorization Guideline

Guideline Name	Xolair (omalizumab)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Xolair (omalizumab)
<p>Allergic Asthma Indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Limitations of Use: Xolair is not indicated for treatment of other allergic conditions. Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus.</p> <p>Chronic Spontaneous Urticaria (CSU) Indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Xolair is not indicated for treatment of other forms of urticaria.</p> <p>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) Indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRWwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.</p>

2 . Criteria

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to severe persistent allergic asthma [1, 2]</p> <p style="text-align: center;">AND</p> <p>2 - Positive skin test or in vitro reactivity to a perennial aeroallergen [1, D]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following [1, F]:</p> <p> 3.1 Both of the following:</p> <p> Patient is 12 years of age or older</p> <p> Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL</p> <p style="text-align: center;">OR</p> <p> 3.2 Both of the following:</p> <p> Patient is 6 years to less than 12 years of age</p> <p> Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL</p> <p style="text-align: center;">AND</p> <p>4 - One of the following</p>	

4.1 Patient is currently being treated with ONE of the following, unless there is a contraindication or intolerance to these medications: [3, A]

4.1.1 Both of the following:

High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)

Additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium)

OR

4.1.2 One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate/salmeterol], Symbicort [budesonide/formoterol]), Breo Ellipta [fluticasone/vilanterol])

OR

4.2 For continuation of prior Xolair therapy

AND

5 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/immunologist

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV1], decreased use of rescue medications)

AND

2 - Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications [3]

AND

3 - Prescribed by or in consultation with one of the following: [G]

Pulmonologist

Allergist/immunologist

Product Name: Xolair

Diagnosis	Chronic Spontaneous Urticaria (CSU)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic spontaneous urticaria [1]

AND

2 - Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines

AND

3 - Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines

AND

4 - One of the following:

4.1 Patient has tried and had an inadequate response or intolerance at least TWO of the following additional therapies: [6, 7]

Doxepin

H1 antihistamine

H2 antagonist (e.g., famotidine, cimetidine)

Hydroxyzine

Leukotriene receptor antagonist (e.g., montelukast)

OR

4.2 For continuation of prior Xolair therapy

AND

5 - Prescribed by or in consultation with one of the following:

Allergist/immunologist

Dermatologist

Product Name: Xolair

Diagnosis

Chronic Spontaneous Urticaria (CSU)

Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced at least one of the following:</p> <ul style="list-style-type: none"> Reduction in itching severity from baseline Reduction in the number of hives from baseline 	

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 All of the following:</p> <p style="padding-left: 40px;">2.1.1 Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) [8, 9]</p>	

AND

2.1.2 Presence of at least 2 of the following symptoms for at least 12 weeks:

Nasal blockage/obstruction/congestion

Nasal discharge (anterior/posterior nasal drip)

Facial pain/pressure

Reduction or loss of smell

AND

2.1.3 Systemic corticosteroid treatment for CRSwNP at least once in the last two years or prior CRSwNP surgery > 6 months ago

AND

2.1.4 Used in combination with another agent for CRSwNP [H]

OR

2.2 For continuation of prior Xolair therapy

AND

3 - Prescribed by or in consultation with one of the following:

Allergist/Immunologist

Otolaryngologist

Pulmonologist

Product Name: Xolair	
Diagnosis	Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale])</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <p style="padding-left: 40px;">Allergist/Immunologist</p> <p style="padding-left: 40px;">Otolaryngologist</p> <p style="padding-left: 40px;">Pulmonologist</p>	

3 . Background

Clinical Practice Guidelines	
<p>The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention: Table 1. Low, medium and high daily doses of inhaled corticosteroids in adolescents and adults 12 years and older [3]</p>	
Inhaled corticosteroid	Total Daily ICS Dose (mcg)

	Low	Medium	High
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	> 500-1000	> 1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle*, HFA)	100-200	> 200-400	> 400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	> 400-800	> 800
Ciclesonide (pMDI, extrafine particle*, HFA)	80-160	> 160-320	> 320
Fluticasone furoate (DPI)	100		200
Fluticasone propionate (DPI)	100-250	> 250-500	> 500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	> 250-500	> 500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400		> 400
<p>DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; ICS: inhaled corticosteroid; N/A: not applicable; pMDI: pressurized metered dose inhaler (non-chlorofluorocarbon formulations); ICS by pMDI should be preferably used with a spacer *See product information.</p> <p><i>This is not a table of equivalence</i>, but instead, suggested total daily doses for the 'low', 'medium' and 'high' dose ICS options for adults/adolescents, based on available studies and product information. Data on comparative potency are not readily available and therefore this table does NOT imply potency equivalence. Doses may be country -specific depending on local availability, regulatory labelling and clinical guidelines.</p> <p>For new preparations, including generic ICS, the manufacturer's information should be reviewed carefully; products containing the same molecule may not be clinically equivalent.</p>			

4 . Endnotes

National treatment guidelines recommend the combination of an inhaled glucocorticosteroid and a long-acting beta2-agonist for the treatment of moderate persistent or severe persistent asthma. [2-5]

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention update recommends that patients with asthma should be reviewed regularly to monitor their symptom control, risk factors and occurrence of exacerbations, as well as to document the response to any treatment changes. Ideally, response to Type 2-targeted therapy should be re-evaluated every 3-6 months, including re-evaluation of the need for ongoing biologic therapy for patients with good response to Type 2 targeted therapy. Clinical studies for allergic asthma evaluated an initial 16-week steroid stable phase in which subjects received omalizumab with a constant dose of inhaled steroids. This 16-week period may not be sufficient amount of time to show reduction in exacerbations. For allergic asthma, initial authorization duration increased from 16 weeks to 6 months. [3, 4]

Asthma treatment can often be reduced, once good asthma control has been achieved and maintained for three months and lung function has hit a plateau. However the approach to stepping down will depend on patient specific factors (e.g., current medications, risk factors). At this time evidence for optimal timing, sequence and magnitude of treatment reductions is limited. It is feasible and safe for most patients to reduce the ICS dose by 25-50% at three month intervals, but complete cessation of ICS is associated with a significant risk of exacerbations [3].

Sensitization to a perennial allergen (e.g., mite, cat, dog) should be required. [4] Xolair is indicated for children and adults (6 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. [1]

For chronic idiopathic urticaria, response observed at 12 weeks (one 24-week trial with data reported at 12 weeks, and one 12-week trial) [1]

Per prescribing information, pretreatment serum total IgE levels of 30 to 700 IU/mL applies to patients 12 years of age and older with asthma. [1]

Referral to an asthma specialist for consultation or comanagement is recommended if Xolair is being considered. [2]

Other agents used for nasal polyps include intranasal corticosteroids and nasal saline.

5 . References

Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2023.

National Heart, Lung, and Blood Institute, National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Institutes of Health Publication No.08-5846. Bethesda, MD, 2007. Available at: <https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma>. Accessed January 9, 2020.

Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.

Per clinical consult with asthma specialist, January 6, 2011.

National Institute for Health and Care Excellence (NICE). Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 64 p. (Technology appraisal guidance; no. 278). Available at <https://www.nice.org.uk/guidance/ta278/resources/omalizumab-for-treating-severe-persistent-allergic-asthma-pdf-82600619176645>. Accessed January 9, 2020.

Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. *J Allergy Clin Immunol*. 2014;133(5):1270-7.

DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 11, 2021.

Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-85.

Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. *Int Forum Allergy Rhinol*. 2016 Feb; Suppl 1:S22-209.

Xospata (gilteritinib)

Prior Authorization Guideline

Guideline Name	Xospata (gilteritinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Xospata (gilteritinib) tablets
Relapsed or Refractory Acute Myeloid Leukemia Indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

2 . Criteria

Product Name: Xospata	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of acute myeloid leukemia (AML)	

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has a FMS-like tyrosine kinase 3 (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

AND

4 - Prescribed by or in consultation with a hematologist or oncologist

Product Name: Xospata	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Xospata therapy	

3 . References

Xospata prescribing information. Astellas Pharma US, Inc. Northbrook, IL. November 2018.

U.S. Food and Drug Administration: List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). Available at: <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/cm301431.htm>. Accessed December 11, 2018.

Prior Authorization Guideline

Guideline Name	Xpovio (selinexor)
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Guideline Note:

Effective Date:	12/15/2023
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1 . Indications

Drug Name: Xpovio (selinexor)
<p>Multiple Myeloma Indicated in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy. Also indicated in combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.</p> <p>Diffuse Large B-cell Lymphoma (DLBCL) Indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.</p>

2 . Criteria

Product Name: Xpovio	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <p style="padding-left: 40px;">Diffuse large B-cell lymphoma (DLBCL)</p> <p style="padding-left: 40px;">Multiple Myeloma</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with an oncologist/hematologist</p>	

Product Name: Xpovio	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

Xpovio Prescribing Information. Karyopharm Therapeutics Inc. Newton, MA. July 2022.

Xtandi (enzalutamide)

Prior Authorization Guideline

Guideline Name	Xtandi (enzalutamide)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Xtandi (enzalutamide)
Castration-resistant prostate cancer (CRPC) Indicated for the treatment of patients with castration-resistant prostate cancer (CRPC).
Metastatic castration-sensitive prostate cancer (mCSPC) Indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

2 . Criteria

Product Name: Xtandi	
Diagnosis	Castration-resistant prostate cancer (CRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-resistant (chemical or surgical) prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Xtandi	
Diagnosis	Castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Xtandi	
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Diagnosis	Castration-resistant prostate cancer (CRPC), Castration-sensitive prostate cancer (mCSPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

Xtandi prescribing information. Astellas Pharma Inc. Northbrook, IL. September 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.1.2020. Available by subscription at:
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed April 2020.

Xuriden (uridine triacetate)

Prior Authorization Guideline

Guideline Name	Xuriden (uridine triacetate)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Criteria

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - Diagnosis of hereditary orotic aciduria [A] AND 2 - Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism [B]	

Product Name: Xuriden	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to Xuriden therapy [C]</p>	

2 . Endnotes

Hereditary orotic aciduria (uridine monophosphate [UMP] synthase deficiency) or HOA is a rare congenital disorder of pyrimidine metabolism caused by a defect in UMP synthase, a bi-functional enzyme that catalyzes the final 2 steps of the de novo pyrimidine biosynthetic pathway in mammalian cells. Ten defects in pyrimidine metabolic pathways have been identified to date; all exhibit autosomal recessive inheritance, however, the ubiquitous presence of pyrimidine-derived compounds underlies the heterogeneity in clinical expression, even within families, thus often making recognition difficult. While the true prevalence of these rare disorders is unknown, inborn errors of pyrimidine metabolism are now increasingly being recognized in adults with partial deficiencies, and so may present from birth onwards. [1-2]

Three subtypes of HOA have been described; alongside clinical presentation (notably macrocytic hypochromic megaloblastic anemia and crystalluria), the ratio of urinary orotidine to orotate provides a means of differentiating the 3 subtypes. The enzyme defect in HOA can be bypassed by the administration of oral uridine which is not Food and Drug Administration-approved, but is available over-the-counter in various dietary/food supplements or as a bulk powder from which doses may be compounded; oral uridine has been used as a treatment for patients with HOA for more than 4 decades. Because uridine is widely used for several non-HOA conditions, the addition of a specialist prescriber requirement was added to reserve the use of XURIDEN for those patients with rare HOA. [1-4]

The recommended starting dosage of oral Xuriden is 60 mg/kg once daily. The dose can be increased to 120 mg/kg (not to exceed 8 grams) once daily for insufficient efficacy, such as the occurrence of one of the following: (1) levels of orotic acid in urine remain above normal or increase above the usual or expected range for the patient, (2) laboratory values (eg, red blood cell or white blood cell indices) affected by hereditary orotic aciduria show evidence of worsening, or (3) worsening of other signs or symptoms of the disease. Case reports have demonstrated that the effects of exogenous uridine were maintained over months and years, as long as treatment continued at sufficient doses (with appropriate dose increases based on body weight increases). Most hematologic abnormalities and orotic aciduria reappeared within days to up to 2 or 3 weeks when

administration of uridine was stopped or the dose was reduced. If treatment was interrupted for longer periods, body weight growth receded. [1]

3 . References

Xuriden Prescribing Information. Wellstat Therapeutics Corporation, February 2017.

Balasubramaniam S, Duley JA, Christodoulou J. Inborn errors of pyrimidine metabolism: clinical update and therapy. *J Inherit Metab Dis.* 2014;37(5):687-98.

Jurecka A. Inborn errors of purine and pyrimidine metabolism. *J Inherit Metab Dis.* 2009;32(2):247-263.

Weinberg ME, Roman MC, Jacob P, et al. Enhanced uridine bioavailability following administration of a triacetyloridine-rich nutritional supplement. *PLoS one.* 2011;6(2).

Xywav (calcium, magnesium, potassium, and sodium oxybates)

Prior Authorization Guideline

Guideline Name	Xywav (calcium, magnesium, potassium, and sodium oxybates)
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Guideline Note:

Effective Date:	3/15/2022
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1 . Indications

Drug Name: Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution
Narcolepsy with Cataplexy (Narcolepsy Type 1) Indicated for the treatment of cataplexy in patients 7 years of age and older with narcolepsy.
Narcolepsy without Cataplexy (Narcolepsy Type 2) Indicated for the treatment of excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy.
Idiopathic Hypersomnia (IH) Indicated for the treatment of idiopathic hypersomnia (IH) in adults.

2 . Criteria

Product Name: Xywav	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1) [A]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study and submission of medical records documenting study results [2-6]</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms of cataplexy are present</p> <p style="text-align: center;">AND</p> <p>3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> Neurologist Psychiatrist Sleep Medicine Specialist 	

Product Name: Xywav	
Diagnosis	Narcolepsy with Cataplexy (Narcolepsy Type 1)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy

OR

2 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy

Product Name: Xywav	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2) [B]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of narcolepsy as confirmed by sleep study and submission of medical records documenting study results [2-6]	
AND	
2 - Symptoms of cataplexy are absent	
AND	
3 - Symptoms of excessive daytime sleepiness (e.g., irrepressible need to sleep or daytime lapses into sleep) are present	
AND	
4 - Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age/weight), or intolerance to both of the following :	

generic modafinil or generic armodafinil

Sunosi

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant

OR

5.2 History of or potential for a substance use disorder

AND

6 - Prescribed by or in consultation with one of the following:

Neurologist

Psychiatrist

Sleep Medicine Specialist

Product Name: Xywav	
Diagnosis	Narcolepsy without Cataplexy (Narcolepsy Type 2)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy	

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH) [C]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of idiopathic hypersomnia as confirmed by sleep study and submission of medical records documenting study results [2-6]</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms of excessive daytime sleepiness (e.g., nap duration of longer than 60 minutes) are present [6]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> Neurologist Psychiatrist Sleep Medicine Specialist 	

Product Name: Xywav	
Diagnosis	Idiopathic Hypersomnia (IH) [C]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy

3 . Endnotes

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) : 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is less than or equal to 110 pg/mL or less than one-third of the mean values obtained in normal subjects with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [2-4]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) : 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, is greater than 110 pg/mL or greater than one-third of the mean values obtained in normal subjects with the same standardized assay) 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [2-4]

International classification of Sleep Disorders (ICSD-3) diagnostic criteria for idiopathic hypersomnia requires all of the following: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months 2. Cataplexy is absent 3. A multiple sleep latency test (MSLT) documents fewer than two sleep-onset rapid eye movement periods (SOREMPs), or no SOREMPs if the REM sleep latency on the preceding polysomnogram was ≤ 15 minutes 4. The presence of at least one of the following: MSLT shows a mean sleep latency of ≤ 8 minutes or Total 24-hour sleep time is ≥ 660 minutes (typically 12 to 14 hours) on 24-hour polysomnography

or by wrist actigraphy in association with a sleep log 5. Insufficient sleep syndrome is ruled out (if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed, preferably confirmed by at least a week of wrist actigraphy) 6. No better explanation by another sleep disorder, medical or psychiatric disorder or use of drugs or medications. [2-6]

4 . References

Xywav Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. August 2021.

International classification of sleep disorders. 3rd ed. Darien, IL: American Academy of Sleep Medicine; 2014.

Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394

Scammell TE. Clinical features and diagnosis of narcolepsy. UpToDate Website. August 2020. www.uptodate.com. Accessed October 12, 2020.

Chevin, Ronald D. Idiopathic Hypersomnia. UpToDate Website. August 2021. www.uptodate.com. Accessed September 6, 2021.

Khan, Zeeshan, Trotti, Lynn Marie. Central Disorders of Hypersomnolence, Focus on the Narcolepsies and Idiopathic Hypersomnia. CHEST 2015 Jul; 148(1):262-273

Yonsa (abiraterone acetate)

Prior Authorization Guideline

Guideline Name	Yonsa (abiraterone acetate)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Yonsa (abiraterone acetate)
Metastatic castration-resistant prostate cancer (mCRPC) Indicated in combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer.

2 . Criteria

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

Product Name: Yonsa

Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

3 . References

Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. March 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.3.2022. Available by subscription at:
https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed May 3, 2022.

Zejula (niraparib)

Prior Authorization Guideline

Guideline Name	Zejula (niraparib)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Zejula (niraparib)
First-Line Maintenance Treatment of Advanced Ovarian Cancer Indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
Maintenance Treatment of Recurrent Germline BRCA-mutated Ovarian Cancer Indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

2 . Criteria

Product Name: Zejula	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

Epithelial ovarian cancer

Fallopian tube cancer

Primary peritoneal cancer

Product Name: Zejula	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

Zejula Prescribing Information. GlaxoSmithKline, LLC. Research Triangle Park, NC. December 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer v.1.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed April 21, 2022.

Prior Authorization Guideline

Guideline Name	Zelboraf (vemurafenib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Zelboraf (vemurafenib)
Melanoma Indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test. It is not recommended for use in patients with wild-type BRAF melanoma.
Erdheim-Chester Disease Indicated for the treatment of patients with Erdheim-Chester Disease with BRAF V600 mutation.

2 . Criteria

Product Name: Zelboraf	
Diagnosis	Melanoma
Approval Length	12 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [2]

Unresectable melanoma

Metastatic melanoma

AND

2 - Cancer is BRAF V600 mutant type as detected by an FDA-approved test (e.g., cobas 4600 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

AND

3 - Prescribed by or in consultation with an oncologist

Product Name: Zelboraf	
Diagnosis	Erdheim-Chester Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Erdheim-Chester disease (ECD)	
AND	
2 - Disease is BRAF V600 mutant type (MT)	

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Zelboraf	
Diagnosis	All Indications
Approval Length	12 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . Endnotes

In the pivotal trial (Trial 1) evaluating treatment naive patients who received Zelboraf (vemurafenib), the median follow-up was 6.2 months and the median progression free survival (PFS) was 5.3 months (95% CI, 4.9 - 6.6). In the pivotal trial (Trial 2) evaluating Zelboraf (vemurafenib) in patients who received prior systemic therapy, the best overall response rate was 52% (95% CI, 43 - 61%), the median time to response was 1.4 months, and the median duration of response was 6.5 months (95% CI, 5.6 - not reached). [1] According to the NCCN melanoma guidelines, Zelboraf (vemurafenib) is associated with a 40-50% response rate in patients with a V600 mutated BRAF gene; however, the median duration of response is only 5 - 6 months. [2]

4 . References

Zelboraf Prescribing Information. Genentech USA, Inc., September 2017.

National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed February 17, 2020.

Zelnorm (tegaserod)

Prior Authorization Guideline

Guideline Name	Zelnorm (tegaserod)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Zelnorm (tegaserod)
Irritable bowel syndrome with constipation Indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C). Limitations of Use: The safety and effectiveness of Zelnorm in men with IBS-C have not been established.

2 . Criteria

Product Name: Zelnorm	
Approval Length	6 weeks [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of irritable bowel syndrome with constipation (IBS-C)	

AND

2 - Patient is female

AND

3 - Age less than 65 years [B]

AND

4 - Trial and failure, contraindication, or intolerance to ONE of the following: [C]

Lactulose

Polyethylene glycol

AND

5 - Trial and failure, contraindication, or intolerance to Linzess

Product Name: Zelnorm	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy	

3 . Endnotes

Authorization limit was set to 6 weeks because Zelnorm should be discontinued in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment. [1]

Zelnorm was removed from the market in 2007 due to evidence of increased risk of heart attacks and strokes but has been re-released after limiting the indication to adult women with IBS-C who are < 65 years of age to define a patient population with low cardiovascular risk. [2]

Osmotic laxatives should be tried/failed first before patients are placed on other therapies due to the favorable tolerability profile. [3]

4 . References

Zelnorm Prescribing Information. Sloan Pharma. Louisville, KY. March 2019.

FDA Center for Drug Evaluation and Research. Zelnorm Medical Review [Application Number 021200, s015]. FDA Web site.
https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/021200Orig1s015MultidisciplineR.pdf. Accessed August 6, 2019.

Moayyedi P, Mearin F, Azpiroz F, et al. Irritability bowel syndrome diagnosis and management: A simplified algorithm for clinical practice. United European Gastroenterology Journal. 2017;5(6):773-788.

Zepatier (elbasvir/grazoprevir)

Prior Authorization Guideline

Guideline Name	Zepatier (elbasvir/grazoprevir)
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Guideline Note:

Effective Date:	11/15/2022
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1 . Indications

Drug Name: Zepatier (elbasvir/grazoprevir)
Chronic Hepatitis C Indicated with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg.

2 . Criteria

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITHOUT baseline NS5A polymorphisms*
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes

*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier

Diagnosis

Chronic Hepatitis C - Genotype 1a: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced WITH baseline NS5A polymorphisms*

Approval Length

16 Week(s)

Guideline Type

Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1a

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

Patient is treatment-naive

Patient has prior failure to peginterferon alfa plus ribavirin treatment

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

AND

4 - Both of the following: [1, A]

4.1 Patient has been tested for the presence of NS5A resistance-associated polymorphisms

AND

4.2 Patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

AND

5 - Used in combination with ribavirin

AND

6 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

7 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

8 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

9 - One of the following:

9.1 Both of the following:

9.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

9.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

9.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Notes

*NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 1b: treatment-naïve or PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1b

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - One of the following:

3.1 Patient is treatment-naive

OR

3.2 Patient has prior failure to peginterferon alfa plus ribavirin treatment

OR

3.3 Both of the following:

Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

Used in combination with ribavirin

AND

4 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: Treatment-naive
Approval Length	12 Week(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic hepatitis C genotype 4</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 40px;">Patient is 12 years of age or older</p> <p style="padding-left: 40px;">Patient weight is at least 30 kg</p> <p style="text-align: center;">AND</p> <p>3 - Patient is treatment-naive</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with one of the following:</p> <p style="padding-left: 40px;">Hepatologist</p> <p style="padding-left: 40px;">Gastroenterologist</p> <p style="padding-left: 40px;">Infectious disease specialist</p> <p style="padding-left: 40px;">HIV specialist certified through the American Academy of HIV Medicine</p> <p style="text-align: center;">AND</p>	

5 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

6 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

7 - One of the following:

7.1 Both of the following:

7.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

7.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

7.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

Product Name: Zepatier	
Diagnosis	Chronic Hepatitis C - Genotype 4: PegIFN/RBV-experienced
Approval Length	16 Week(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of chronic hepatitis C genotype 4

AND

2 - One of the following:

Patient is 12 years of age or older

Patient weight is at least 30 kg

AND

3 - Patient has prior failure to peginterferon alfa plus ribavirin treatment

AND

4 - Used in combination with ribavirin

AND

5 - Prescribed by or in consultation with one of the following:

Hepatologist

Gastroenterologist

Infectious disease specialist

HIV specialist certified through the American Academy of HIV Medicine

AND

6 - Not used in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

AND

7 - Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C) [B]

AND

8 - One of the following:

8.1 Both of the following:

8.1.1 Trial and failure, intolerance, or contraindication to ONE of the following:

Epclusa (sofosbuvir/velpatasvir)

Harvoni (ledipasvir/sofosbuvir)

AND

8.1.2 Trial and failure, contraindication, or intolerance to Mavyret (glecaprevir/pibrentasvir)

OR

8.2 For continuation of prior Zepatier (elbasvir/grazoprevir) therapy

3 . Endnotes

Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to initiation of treatment with Zepatier to determine dosage regimen and duration. In subjects receiving Zepatier for 12 weeks, sustained virologic response (SVR12) rates were lower in genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93. [1]

Zepatier is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh B or C) due to the expected significantly increased grazoprevir plasma concentration and the increased risk of alanine aminotransferase (ALT) elevations. [1]

4 . References

Zepatier Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 2021.

American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. September 2021. <http://www.hcvguidelines.org/full-report-view>. Accessed May 16, 2022.

Prior Authorization Guideline

Guideline Name	Zeposia (ozanimod)
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Guideline Note:

Effective Date:	3/15/2024
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1 . Indications

Drug Name: Zeposia (ozanimod)
Relapsing forms of MS Indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
Ulcerative Colitis Indicated for the treatment of moderately to severely active ulcerative colitis in adults.

2 . Criteria

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Zeposia	
Diagnosis	Multiple Sclerosis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression)	
AND	
2 - Not used in combination with another disease-modifying therapy for MS	
AND	
3 - Prescribed by or in consultation with a neurologist	

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 Weeks [B, 3, 4]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderately to severely active ulcerative colitis</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to one of the following conventional therapies:</p> <p style="padding-left: 40px;">6-mercaptopurine (Purinethol)</p> <p style="padding-left: 40px;">Aminosalicylates (e.g., mesalamine [Asacol, Pentasa, Rowasa], osalazine [Dipentum], Sulfasalazine [Azulfidine, Sulfazine])</p> <p style="padding-left: 40px;">Azathioprine (Imuran)</p> <p style="padding-left: 40px;">Corticosteroids (e.g., prednisone, methylprednisolone)</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p style="padding-left: 20px;">3.1 Trial and failure, contraindication, or intolerance to TWO of the following, or attestation demonstrating a trial may be inappropriate*:</p> <p style="padding-left: 40px;">Humira (adalimumab), Cyltezo, Hadlima, or Brand adalimumab-adbm</p> <p style="padding-left: 40px;">Simponi (golimumab)</p> <p style="padding-left: 40px;">Stelara (ustekinumab)</p>	

Rinvoq (upadacitinib) Xeljanz/XR (tofacitinib/ER) <p style="text-align: center;">OR</p>	
<p>3.2 For continuation of prior therapy</p> <p style="text-align: center;">AND</p>	
<p>4 - Prescribed by or in consultation with a gastroenterologist</p>	
Notes	* Includes attestation that the patient has failed to respond to the TNF inhibitor mechanism of action in the past and should not be made to try a second TNF inhibitor. In this case, only a single step through a preferred agent is required.

Product Name: Zeposia	
Diagnosis	Ulcerative Colitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

3 . Endnotes

According to the National MS Society, of the four disease courses that have been identified in MS, relapsing-remitting MS (RRMS) is characterized primarily by relapses, and secondary-progressive MS (SPMS) has both relapsing and progressive characteristics. These two constitute “relapsing forms of MS” if they describe a disease course that is characterized by the occurrence of relapses. [2] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [1]

In the TRUE NORTH induction trial, the primary response of clinical remission, as defined by the 3-component Mayo score without the physician global assessment, was assessed at week 10. The initial authorization length was set to be 12 weeks to also account for logistical purposes. [3]

4 . References

Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline: Disease-modifying therapies for adults with multiple sclerosis. *Neurology* 2018;90:777-788.

National Multiple Sclerosis Society. Types of MS. Available at: <https://www.nationalmssociety.org/What-is-MS/Types-of-MS>. Accessed March 29, 2019.

Zeposia Prescribing Information. Celgene Corporation. Summit, NJ. May 2021.

Per clinical consultation with gastroenterologist, July 9, 2021.

Prior Authorization Guideline

Guideline Name	Zokinvy (lonafarnib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Zokinvy (lonafarnib)

Hutchinson-Gilford Progeria Syndrome (HGPS) Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m² and above to reduce the risk of mortality in Hutchinson-Gilford Progeria Syndrome (HGPS). Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

Progeroid Laminopathies Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m² and above for the treatment of processing-deficient Progeroid Laminopathies with either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations. Limitations of Use: ZOKINVY is not indicated for other Progeroid Syndromes or processing-proficient Progeroid Laminopathies. Based upon its mechanism of action, ZOKINVY would not be expected to be effective in these populations.

2 . Criteria

Product Name: Zokinvy

Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of Hutchinson-Gilford Progeria Syndrome</p> <p style="text-align: center;">OR</p> <p>1.2 For treatment of processing-deficient Progeroid Laminopathies with one of the following:</p> <p style="padding-left: 40px;">Heterozygous LMNA mutation with progerin-like protein accumulation</p> <p style="padding-left: 40px;">Homozygous or compound heterozygous ZMPSTE24 mutations</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 12 months of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a body surface area of 0.39 m² and above</p>	

3 . References

Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. November 2020.

Zolinza (vorinostat)

Prior Authorization Guideline

Guideline Name	Zolinza (vorinostat)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Zolinza (vorinostat)
Cutaneous T-cell Lymphoma Indicated for treatment of cutaneous manifestations in patients with cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease on or following two systemic therapies.

2 . Criteria

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of cutaneous T-cell lymphoma	

AND

2 - One of the following: [2]

2.1 Patient has progressive, persistent or recurrent disease on or following 2 systemic therapies (e.g., extracorporeal photopheresis [ECP], systemic retinoids, interferons, etc.) [A]

OR

2.2 History of contraindication or intolerance to other systemic therapies (e.g., Adcetris [brentuximab vedotin, Cytoxan [cyclophosphamide], Poteligeo [mogamulizumab], etc) [A]

AND

3 - Prescribed by or in consultation with a hematologist/oncologist

Product Name: Zolinza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on Zolinza therapy	

3 . Endnotes

Examples of systemic therapies include (but are not limited to): [2] • Adcetris (brentuximab vedotin) • Cytoxan (cyclophosphamide) • Doxil (pegylated doxorubicin) • Extracorporeal photochemotherapy • Folutyn (pralatrexate) • Gemzar (gemcitabine) • Interferon-alpha • Leukeran (chlorambucil) • Nipent (pentostatin) • Poteligeo (mogamulizumab) • Targretin (bexarotene) • Temodar (temozolamide) • Toposar (etoposide) • Trexall (methotrexate) • Velcade (bortezomib)

4 . References

Zolinza Prescribing Information. Merck & Co, Inc. Whitehouse Station, NJ. April 2013.

National comprehensive cancer network (NCCN) clinical practice guidelines in oncology:

Primary cutaneous lymphomas. v.2.2019. Available at:

https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed September 16, 2019.

Zoryve (roflumilast)

Prior Authorization Guideline

Guideline Name	Zoryve (roflumilast)
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Guideline Note:

Effective Date:	4/1/2023
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1 . Indications

Drug Name: Zoryve (roflumilast) cream
Plaque Psoriasis (PsO) Indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

2 . Criteria

Product Name: Zoryve	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of plaque psoriasis	

AND

2 - Patient is 12 years of age or older

AND

3 - Minimum duration of a 4 week trial and failure, contraindication, or intolerance to TWO of the following topical therapies: [2]

Corticosteroids (e.g., betamethasone, clobetasol)

Vitamin D analogs (e.g., calcitriol, calcipotriene)

Tazarotene

Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

Anthralin

Coal tar

AND

4 - Prescribed by or in consultation with a dermatologist

Product Name: Zoryve	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Documentation of positive clinical response to therapy as evidenced by one of the following: [2]	

Reduction in the body surface area (BSA) involvement from baseline

Improvement in symptoms (e.g., pruritus, inflammation) from baseline

3 . References

Zoryve Prescribing Information. Arcutis Biotherapeutics Inc. Westlake Village, CA. July 2022.

Elmets CA, Korman NJ, Farley Prater E, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures. *J Am Acad Dermatol* 2021;84:432-70.

Ztalmy (ganaxolone)

Prior Authorization Guideline

Guideline Name	Ztalmy (ganaxolone)
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Guideline Note:

Effective Date:	2/15/2023
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1 . Indications

Drug Name: Ztalmy (ganaxolone)
Seizures Indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older.

2 . Criteria

Product Name: Ztalmy	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD)	

AND

2 - Patient has a mutation in the CDKL5 gene

AND

3 - Patient is 2 years of age or older

AND

4 - Patient is experiencing motor seizures (e.g., bilateral tonic, generalized tonic-clonic, bilateral clonic, atonic, focal, or bilateral tonic-clonic)

AND

5 - One of the following:

5.1 Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine)

OR

5.2 For continuation of prior therapy

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ztalmy	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by a reduction in the frequency of seizures from baseline

3 . References

Ztalmy Prescribing Information. Marinus Pharmaceuticals, Inc. Radnor, PA. June 2022.

Zurzuvae (zuranolone)

Prior Authorization Guideline

Guideline Name	Zurzuvae (zuranolone)
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Guideline Note:

Effective Date:	4/1/2024
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1 . Indications

Drug Name: Zurzuvae (zuranolone)
Postpartum Depression (PPD) Indicated for the treatment of PPD in women 18 years of age and older

2 . Criteria

Product Name: Zurzuvae	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
Approval Criteria 1 - One of the following: 1.1 Diagnosis of severe postpartum depression (PPD)	

OR

1.2 Both of the following:

1.2.1 Diagnosis of mild to moderate postpartum depression (PPD)

AND

1.2.2 Trial and failure, contraindication or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine)

AND

2 - Patient is 18 years of age or older

AND

3 - Onset of symptoms in the third trimester or within 4 weeks of delivery

AND

4 - Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae

3 . References

Zurzuvae Prescribing Information. Biogen MA Inc. November 2023.

Zydelig (idelalisib)

Prior Authorization Guideline

Guideline Name	Zydelig (idelalisib)
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Guideline Note:

Effective Date:	8/15/2022
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1 . Indications

Drug Name: Zydelig (idelalisib)
Relapsed Chronic Lymphocytic Leukemia Indicated, in combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities. Limitation of Use: Zydelig is not indicated and is not recommended for first line treatment of patients with CLL.

2 . Criteria

Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of Chronic Lymphocytic Leukemia (CLL)

AND

2 - Patient has relapsed on at least one prior therapy (e.g., purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab])

AND

3 - Used in combination with Rituxan (rituximab)* [2]

AND

4 - Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (e.g., coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD], etc.)

AND

5 - Prescribed by or in consultation with an oncologist/hematologist

Notes	*This drug may require prior authorization.
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Product Name: Zydelig	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient does not show evidence of progressive disease while on therapy	

3 . References

Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed September 9, 2021.

Zykadia (ceritinib)

Prior Authorization Guideline

Guideline Name	Zykadia (ceritinib)
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Guideline Note:

Effective Date:	2/1/2022
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1 . Indications

Drug Name: Zykadia (ceritinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

2 . Criteria

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of non-small cell lung cancer (NSCLC) [2, 3]	

AND

2 - One of the following: [2, 3]

Disease is metastatic

Disease is recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test or at a Clinical Laboratory Improvement Amendments-approved facility [2, 3]

AND

4 - One of the following:

4.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:

Alecensa (alectinib)

Alunbrig (brugatinib)

OR

4.2 For continuation of prior therapy

AND

5 - Prescribed by or in consultation with an oncologist

Product Name: Zykadia	
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient does not show evidence of progressive disease while on therapy</p>	

3 . References

Zykadia Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2019.

The NCCN Drugs and Biologics Compendium. Available at:
http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 27, 2020.

National Comprehensive Cancer Network (NCCN) Non-small cell lung cancer guideline. v.4.2020. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed May 27, 2020.

Zytiga (abiraterone acetate)

Prior Authorization Guideline

Guideline Name	Zytiga (abiraterone acetate)
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Guideline Note:

Effective Date:	11/1/2023
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1 . Indications

Drug Name: Zytiga (abiraterone acetate)
Metastatic castration-resistant prostate cancer (mCRPC) Indicated for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in combination with prednisone.
Metastatic castration-sensitive prostate cancer (mCSPC) Indicated for the treatment of patients with metastatic high risk castration-sensitive prostate cancer (mCSPC) in combination with prednisone.

2 . Criteria

Product Name: Generic abiraterone acetate, Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

AND

3 - Both of the following (applies to BRAND Zytiga only):

3.1 Trial and failure or intolerance to generic abiraterone acetate

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic abiraterone acetate, Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - Prescribed by or in consultation with one of the following:

Oncologist

Urologist

AND

3 - Both of the following (applies to BRAND Zytiga only):

3.1 Trial and failure or intolerance to generic abiraterone acetate

AND

3.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

Product Name: Generic abiraterone acetate, Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer, castration-resistant prostate cancer
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease while on therapy

AND

2 - Both of the following (applies to BRAND Zytiga only):

2.1 Trial and failure or intolerance to generic abiraterone acetate

AND

2.2 Submission of documentation (e.g., chart notes, lab values, literature, or compendia support, etc.) documenting ONE of the following:

Allergic response or intolerance to one of the inactive ingredients of the generic drug

Inadequate therapeutic response to the generic product based on objective measures and clinical reason why the branded product is expected to provide a better therapeutic effect (as supported by submitted medical literature or drug compendium)

3 . References

Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. August 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer. v.4.2018. Available by subscription at:
http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf. Accessed September 18, 2018.