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Actemra (tocilizumab)

Prior Authorization Guideline

Guideline ID	GL-133933
Guideline Name	Actemra (tocilizumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/6/2010
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 05/20/2021 ; 04/20/2022 ; 05/19/2022 ; 10/19/2022 ; 12/14/2022 ; 02/16/2023 ; 05/18/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Actemra (tocilizumab IV), Actemra (tocilizumab SC)
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). **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)** Indicated for the treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older. **Giant Cell Arteritis (GCA)** Indicated for the treatment of giant cell arteritis (GCA) in adult patients.
Drug Name: Actemra (tocilizumab IV)

Cytokine Release Syndrome Indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome in adults and pediatric patients 2 years of age and older. **Coronavirus Disease 2019 (COVID-19)** Indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Drug Name: Actemra (tocilizumab SC)
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).

2 . Criteria

Product Name: Actemra IV or SC	
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

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 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
- 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Actemra IV or SC	
Diagnosis	Rheumatoid Arthritis (RA)
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

Product Name: Actemra IV or 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 IV or SC	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA)
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 [4]:

- 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 IV or SC	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active polyarticular juvenile idiopathic arthritis

AND

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]:

- leflunomide
- methotrexate

AND

3 - Prescribed by or in consultation with a rheumatologist

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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Xeljanz (tofacitinib)

OR

4.2 For continuation of 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Actemra IV or SC	
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, 5]:

- 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 IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell arteritis

AND

2 - Prescribed by or in consultation with a rheumatologist

AND

3 - Trial and failure, contraindication, or intolerance to a glucocorticoid

Product Name: Actemra IV or SC	
Diagnosis	Giant Cell Arteritis (GCA)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

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

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following [6-8]:

1.1 Exclusion of other known causes of interstitial lung disease (ILD)

AND

1.2 One of the following:

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

OR

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 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 - Patient demonstrates positive clinical response to therapy.

Product Name: Actemra IV	
Diagnosis	Cytokine Release Syndrome (CRS) Risk due to CAR T-Cell Therapy

Approval Length	2 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy (e.g., Kymriah [tisagenlecleucel], Yescarta [axicabtagene ciloleucel])

AND

2 - Prescribed by or in consultation with an oncologist or hematologist

Product Name: Actemra IV	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Days [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Currently receiving systemic corticosteroids

AND

4 - Patient requires one of the following:

- Supplemental oxygen
- Non-invasive mechanical ventilation
- Invasive mechanical ventilation
- Extracorporeal membrane oxygenation (ECMO)

3 . Endnotes

A. Patients should have Actemra on board for initial CAR T-cell therapy and be evaluated for signs and symptoms of CRS for at least 4 weeks after, up to a total of 4 doses of Actemra with at least 8 hours between doses. [1]
B. The recommended dosage of Actemra for treatment of adult patients with COVID-19 is 8 mg/kg administered as a single 60-minute intravenous infusion. If clinical signs or symptoms worsen or do not improve after the first dose, one additional infusion of Actemra may be administered at least 8 hours after the initial infusion. [1]

4 . References

1. Actemra Prescribing Information. Genentech, Inc. South San Francisco, CA. December 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. 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.
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.
7. 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.
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.

5 . Revision History

Date	Notes
9/28/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Actimmune (interferon gamma-1b)

Prior Authorization Guideline

Guideline ID	GL-123571
Guideline Name	Actimmune (interferon gamma-1b)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	3/21/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

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 . Background

Benefit/Coverage/Program Information
Effective date Prior to 3/8/2023 Updates the effective date was 1/1/2021

4 . References

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

5 . Revision History

Date	Notes
4/11/2023	Annual review

Adakveo (crizanlizumab-tmca)

Prior Authorization Guideline

Guideline ID	GL-132631
Guideline Name	Adakveo (crizanlizumab-tmca)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/15/2020
P&T Revision Date:	02/13/2020 ; 01/20/2021 ; 01/19/2022 ; 01/18/2023

1 . Indications

Drug Name: Adakveo (crizanlizumab-tmca)
Sickle Cell Disease Indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.

2 . Criteria

Product Name: Adakveo	
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 16 years of age and older

AND

3 - Documentation of 2 vaso-occlusive events that required medical facility visits and treatments in the past 12 months (e.g., sickle cell crisis, acute pain episodes, acute chest syndrome, hepatic sequestration, splenic sequestration, priapism) [1, 2]

AND

4 - Trial and failure or inadequate response, contraindication, or intolerance to one of the following: [3, 4, 5, 6]

- Hydroxyurea
- L-glutamine (i.e., Endari)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in annual rate of vaso-occlusive events, increased time between each vaso-occlusive event)

3 . References

1. Adakveo (crizanlizumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2022.
2. Ataga K, Kutlar A, Kanter J et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. New England Journal of Medicine. 2017;376(5):429-439. doi:10.1056/nejmoa1611770.
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 6, 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.
5. Niihara Y, Miller S, Kanter J et al. A Phase 3 Trial of l-Glutamine in Sickle Cell Disease. New England Journal of Medicine. 2018;379(3):226-235. doi:10.1056/nejmoa1715971.
6. Brandow A, Carroll C, Creary S et al. American Society of Hematology 2020 guidelines for sickle cell disease: management of acute and chronic pain. Blood Adv. 2020;4(12):2656-2701. doi:10.1182/bloodadvances.2020001851.

Adalimumab

Prior Authorization Guideline

Guideline ID	GL-135622
Guideline Name	Adalimumab

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/17/2003
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 04/21/2021 ; 11/18/2021 ; 10/19/2022 ; 12/14/2022 ; 05/18/2023 ; 07/19/2023 ; 10/18/2023 ; 11/16/2023

Note:

This guideline applies to the following Tier 2 products: Humira, Amjevita, Cyltezo, Hyrimoz by Sandoz, and Brand Adalimumab-adaz. 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: Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hyrimoz (adalimumab-adaz)

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*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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 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	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Rheumatoid Arthritis (RA)
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	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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 [4]:

- leflunomide
- methotrexate

Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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

Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Psoriatic Arthritis (PsA)
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, 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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- 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

Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Plaque Psoriasis (PsO)
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 ONE of the following [1, 6]:

- Reduction the body surface area (BSA) involvement from baseline

• Improvement in symptoms (e.g., pruritus, inflammation) from baseline	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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]	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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, 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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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 (CDAI) 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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Crohn’s disease (CD)
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, 9, 10]:

- 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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 Week(s)
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 [11, 12]:

- 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: [11, 12]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND **4** - Prescribed by or in consultation with a gastroenterologist	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 For patients who initiated Humira therapy within the past 12 weeks, patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy

OR

1.2 For patients who have been maintained on Humira therapy for longer than 12 weeks, patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 11, 12]:

- 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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III) **AND** **2** - Prescribed by or in consultation with a dermatologist	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Patient demonstrates positive clinical response to therapy	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
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	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

Product Name: Humira*, Amjevita (Tier 2 or Preferred)*, Cyltezo*, Hyrimoz (Tier 2 or Preferred, Sandoz manufacturer)*, Brand Adalimumab-adaz*	
Diagnosis	Uveitis (UV)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Patient demonstrates positive clinical response to therapy	
Notes	* For Amjevita with NDC that starts with 55513, Hyrimoz with NDC tha t starts with 61314, and all other products, approve at NDC list “ADALI MUMPA”. If Amjevita has NDC that starts with 72511 or Hyrimoz has NDC that starts with 83457, approve at NDC list "OOADALIMUM".

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. Amjevita Prescribing Information. Amgen Inc. Thousand Oaks, CA. August 2023.
14. Cyltezo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.

15. Hyrimoz Prescribing Information. Sandoz Inc. Princeton, NJ. September 2023.

4 . Revision History

Date	Notes
11/2/2023	Annual review - Updated standard reauth criteria verbiage to "Patient demonstrates..."

Prior Authorization Guideline

Guideline ID	GL-126714
Guideline Name	Afinitor, Afinitor Disperz (everolimus) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	8/18/2009
P&T Revision Date:	02/13/2020 ; 05/15/2020 ; 05/20/2021 ; 11/18/2021 ; 01/19/2022 ; 05/19/2022 ; 05/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Afinitor (everolimus tablet)
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. **Advanced Renal Cell Carcinoma (RCC)** Indicated for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib. **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. **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. **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.

Neuroendocrine Tumors of Gastrointestinal or Lung Origin Indicated for the treatment of adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of 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

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced

- Metastatic

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

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

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Neuroendocrine Tumors of Pancreatic Origin (PNET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive neuroendocrine tumors of pancreatic origin

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

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

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

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

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure with one of the following*:

- Sutent (sunitinib)
- Nexavar (sorafenib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Notes	*Criterion is part of the FDA-approved label.

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

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

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

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Renal Angiomyolipoma with Tuberous Sclerosis Complex (TSC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

AND

3 - Prescribed by or in consultation with a nephrologist

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 Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

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

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)
Guideline Type	Non Formulary

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 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

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

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Notes	*Criterion is part of the FDA-approved label.

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

Product Name: Brand Afinitor, Generic everolimus tablet	
Diagnosis	Breast cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of hormone receptor positive, HER-2 negative advanced breast cancer

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to one of the following*:

- Femara (letrozole)
- Arimidex (anastrozole)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

Notes	*Criterion is part of the FDA-approved label.

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:

- Unresectable, locally advanced disease
- Metastatic disease

AND

3 - Trial and failure or intolerance to generic everolimus tablet (applies to Brand Afinitor only)

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

Product Name: Brand Afinitor, Generic everolimus tablet

Diagnosis	Neuroendocrine tumors of gastrointestinal or lung origin
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of progressive, well-differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung origin

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 everolimus tablet (applies to Brand Afinitor only)

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 - Trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only)

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

Product Name: Brand Afinitor Disperz, Generic everolimus tablet for oral suspension	
Diagnosis	TSC-associated Partial-onset Seizures
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of TSC-associated partial-onset seizures

AND

2 - Patient is 2 years of age or older

AND **3** - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic everolimus tablet for oral suspension (applies to Brand Afinitor Disperz only) **AND** **4** - Prescribed by or in consultation with a neurologist

3 . References

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

4 . Revision History

Date	Notes
6/15/2023	Removed Oncologist specialist requirement

Aldurazyme (laronidase)

Prior Authorization Guideline

Guideline ID	GL-131298
Guideline Name	Aldurazyme (laronidase)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/2/2004
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 6/21/2023

1 . Indications

Drug Name: Aldurazyme (laronidase)
Mucopolysaccharidosis I (MPS I) Indicated for adult and pediatric patients with Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I) and for patients with the Scheie form who have moderate to severe symptoms. The risks and benefits of treating mildly affected patients with the Scheie form have not been established. Aldurazyme has not been evaluated for effects of the central nervous system manifestations of the disorder.

2 . Criteria

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

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hurler or Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I)

OR

1.2 Diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) in patients with moderate to severe symptoms

Product Name: Aldurazyme	
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. Aldurazyme Prescribing Information, BioMarin Pharmaceutical Inc. Novato, CA. December 2019.

4 . Revision History

Date	Notes
8/22/2023	Program update to standard reauthorization language. No changes t o clinical intent

Alecensa (alectinib)

Prior Authorization Guideline

Guideline ID	GL-127536
Guideline Name	Alecensa (alectinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 08/19/2021 ; 05/19/2022 ; 06/21/2023 ; 7/19/2023

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

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.

4 . Revision History

Date	Notes
7/5/2023	update guideline

Alfa Interferons

Prior Authorization Guideline

Guideline ID	GL-126996
Guideline Name	Alfa Interferons

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Intron A (interferon alfa-2b)
Hairy Cell Leukemia Indicated for the treatment of patients 18 years of age or older with hairy cell leukemia. **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. **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. **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. **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.

Chronic Hepatitis C Indicated for the treatment of chronic hepatitis C in patients 18 years of 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/mm^3 - Platelets - adults greater than or equal to 100,000/mm^3, pediatrics greater than or equal to 150,000/mm^3. 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).

2 . Criteria

Product Name: Intron A	
Diagnosis	Chronic Hepatitis C
Approval Length	48 Week(s)

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C

AND

2 - Patients without decompensated liver disease**

AND

3 - For patients who have not previously been treated with interferon

AND

4 - One of the following:

- Contraindication or intolerance to ribavirin
- 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

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

Approval Criteria

1 - Diagnosis of chronic hepatitis B infection

AND

2 - Patients without decompensated liver disease**

Notes	**Defined as Child-Pugh Class B or C

Product Name: Pegasys	
Diagnosis	Chronic Hepatitis C
Approval Length	28 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C infection

AND

2 - Patient without decompensated liver disease**

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	
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 Both of the following:

1.3.1 Diagnosis of metastatic renal cell carcinoma

AND

1.3.2 Used in combination with Avastin (bevacizumab)

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

4 . Revision History

Date	Notes
6/22/2023	Removed Oncology specialist requirement

Alpha-1 Proteinase Inhibitors

Prior Authorization Guideline

Guideline ID	GL-134002
Guideline Name	Alpha-1 Proteinase Inhibitors

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/25/2016
P&T Revision Date:	03/18/2020 ; 01/20/2021 ; 03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 3/15/2023

1 . Indications

Drug Name: Aralast NP (alpha-1-proteinase inhibitor [human])
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.
Drug Name: Glassia (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 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 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 - Patient demonstrates 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 µmol/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 2022.
2. Zemaira Prescribing Information. CSL Behring LLC. Kankakee, IL. September 2022.
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. January 2022.
5. Glassia Prescribing Information. Baxalta US Inc. Lexington, MA. September 2022.
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.

5 . Revision History

Date	Notes

9/29/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Ampyra (dalfampridine) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-135330
Guideline Name	Ampyra (dalfampridine) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/6/2010
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 07/20/2022 ; 06/21/2023 ; 6/21/2023

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 - For brand Ampyra, trial and failure or intolerance to generic dalfampridine extended-release

AND

5 - Prescribed by or in consultation with a neurologist

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

Approval Criteria

1 - Physician confirmation that the patient's walking improved with therapy

AND

2 - 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

3 - For brand Ampyra, trial and failure or intolerance to generic dalfampridine extended-release

Product Name: Brand Ampyra	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multiple sclerosis [A]

AND

2 - Submission of medical records (e.g., chart notes) documenting physician confirmation that patient has difficulty walking (e.g., timed 25-foot walk test) [B]

AND

3 - Submission of medical records (e.g., chart notes) documenting 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 - Submission of medical records (e.g., chart notes) documenting trial and failure or intolerance to generic dalfampridine extended-release **AND** **5** - Prescribed by or in consultation with a neurologist

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. November 2021.
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.

5 . Revision History

Date	Notes
10/25/2023	Added t/f requirement to generic dalfampridine

Apokyn

Prior Authorization Guideline

Guideline ID	GL-121095
Guideline Name	Apokyn

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	10/2/2004
P&T Revision Date:	05/20/2021 ; 03/16/2022 ; 3/15/2023

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

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Generic apomorphine hydrochloride inj	
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. 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.

4 . Revision History

Date	Notes
3/16/2023	2023 Annual Review.

Bavencio (avelumab) injection

Prior Authorization Guideline

Guideline ID	GL-133799
Guideline Name	Bavencio (avelumab) injection

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	5/18/2017
P&T Revision Date:	05/14/2020 ; 08/13/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Bavencio (avelumab)
Merkel Cell Carcinoma (MCC) Indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). **Urothelial Carcinoma (UC)** Indicated for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy. Indicated for the treatment of patients with locally advanced or metastatic UC who: 1) have disease progression during or following platinum-containing chemotherapy, or 2) have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. **Renal Cell Carcinoma (RCC)** Indicated for use in combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

2 . Criteria

Product Name: Bavencio	
Diagnosis	Merkel Cell Carcinoma (MCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic Merkel cell carcinoma

AND

2 - Patient is 12 years of age or older

Product Name: Bavencio	
Diagnosis	Urothelial Carcinoma (UC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of urothelial carcinoma

AND

2 - Disease is one of the following:

- Locally advanced
- Metastatic

AND

3 - One of the following:

3.1 Patient has disease progression during or following platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

OR

3.2 Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

OR

3.3 Both of the following:

3.3.1 Used as maintenance treatment

AND

3.3.2 Patient has not progressed with first-line platinum-containing chemotherapy (e.g., cisplatin, carboplatin)

Product Name: Bavencio	
Diagnosis	Renal Cell Carcinoma (RCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND **2** - Used as first-line treatment in combination with Inlyta (axitinib)

Product Name: Bavencio	
Diagnosis	Merkel Cell Carcinoma (MCC), Urothelial Carcinoma (UC), 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. Bavencio Prescribing Information. EMD Serono, Inc. Rockland, MA. September 2023.

4 . Revision History

Date	Notes
9/28/2023	Updated background sections due to full FDA approval for MCC; no criteria changes

Beleodaq (belinostat)

Prior Authorization Guideline

Guideline ID	GL-127074
Guideline Name	Beleodaq (belinostat)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/14/2014
P&T Revision Date:	02/18/2021 ; 02/17/2022 ; 03/15/2023 ; 7/19/2023

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)

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. December 2022.
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 27, 2023.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Prior Authorization Guideline

Guideline ID	GL-126796
Guideline Name	Bendamustine Agents - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	9/18/2019
P&T Revision Date:	04/15/2020 ; 08/13/2020 ; 08/19/2021 ; 01/19/2022 ; 07/20/2022 ; 02/16/2023 ; 03/15/2023 ; 05/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Belrapzo
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Bendamustine
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Drug Name: Bendeka
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Treanda
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.
Drug Name: Vivimusta
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established. **Non-Hodgkin Lymphoma (NHL)** Indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

2 . Criteria

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of chronic lymphocytic leukemia (CLL)	

AND

2 - One of the following:

2.1 Trial and failure, or intolerance to generic bendamustine

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [A, C]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

AND

2 - One of the following:

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

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 for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

AND

3 - One of the following:

3.1 Trial and failure, or intolerance to generic bendamustine

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Bendeka, Belrapzo, Brand Bendamustine, Brand Treanda, Vivimusta	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [B, D]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

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 generic bendamustine

OR

3.2 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 for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Generic bendamustine	
Diagnosis	Chronic lymphocytic leukemia (CLL)
Approval Length	6 Month(s) [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL)

Product Name: Generic bendamustine	
Diagnosis	Non-Hodgkin lymphoma (NHL)
Approval Length	6 Month(s) [D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of indolent B-cell non-Hodgkin lymphoma (NHL)

AND

2 - Disease has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen

3 . Endnotes

A. For Bendeka: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [3]
B. For Bendeka: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 10 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [3]
C. For Belrapzo, Bendamustine, Treanda: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles. [1, 2, 4]
D. For Belrapzo, Bendamustine, Treanda: The recommended dose for non-Hodgkin lymphoma (NHL) is 120 mg/m2 administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles. [1, 2, 4]
E. For Vivimusta: The recommended dose for chronic lymphocytic leukemia (CLL) is 100 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 28-day cycle for up to 6 cycles. [5]
F. For Vivimusta: The recommended dose for non-Hodgkin lymphoma (NHL) is 20 mg/m2 administered intravenously over 20 minutes on Days 1 and 2 of a 21-day cycle for up to 8 cycles. [5]

4 . References

1. Belrapzo prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. June 2022.
2. Bendamustine prescribing information. Eagle Pharmaceuticals, Inc. Woodcliff Lake, NJ. May 2019.
3. Bendeka prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. October 2021.
4. Treanda prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. June 2021.

5. Vivimusta prescribing information. Slayback Pharma LLC. Princeton, NJ. December 2022.

5 . Revision History

Date	Notes
6/18/2023	2023 Annual Review

Benlysta (belimumab)

Prior Authorization Guideline

Guideline ID	GL-134039
Guideline Name	Benlysta (belimumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/12/2011
P&T Revision Date:	10/16/2019 ; 08/13/2020 ; 02/18/2021 ; 08/19/2021 ; 12/15/2021 ; 08/18/2022 ; 09/21/2022 ; 04/19/2023 ; 08/17/2023 ; 8/17/2023

1 . Indications

Drug Name: Benlysta (belimumab IV), Benlysta (belimumab SC)
Systemic Lupus Erythematosus (SLE) Indicated for the treatment of patients aged 5 years and older with active 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 IV or Benlysta SC	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

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]

AND

3 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

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]

AND

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]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - One of the following:

- For Benlysta IV, patient is 5 years of age or older
- For Benlysta SC, patient is 18 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

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

- Nephrologist
- Rheumatologist

Product Name: Benlysta IV or Benlysta SC	
Diagnosis	All indications listed above
Approval Length	6 months [2, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., decrease or stabilization of symptoms, improvement in functional impairment, decrease of corticosteroid dose, decrease in pain medications)

Product Name: Benlysta IV	
Diagnosis	Systemic lupus erythematosus
Approval Length	6 months [A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active systemic lupus erythematosus (SLE)

AND

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]

AND

3 - Patient is 5 years of age or older

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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]

AND

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]

AND

6 - Prescribed by or in consultation with a rheumatologist

Product Name: Benlysta IV	
Diagnosis	Lupus nephritis
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active lupus nephritis

AND

2 - Patient is 5 years of age or older

AND

3 - Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide) [1, 4]

AND

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

- Nephrologist
- Rheumatologist

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. February 2023.
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.

5 . Revision History

Date	Notes
9/29/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Bevacizumab - PA, NF

Prior Authorization Guideline

Guideline ID	GL-133094
Guideline Name	Bevacizumab - PA, NF

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	02/13/2020 ; 03/18/2020 ; 08/13/2020 ; 02/18/2021 ; 01/19/2022 ; 02/17/2022 ; 07/20/2022 ; 03/15/2023 ; 04/19/2023 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Avastin (bevacizumab)
Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer. **Non-Squamous Non–Small Cell Lung Cancer (NSCLC)** Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel. **Glioblastoma** Indicated for the treatment of recurrent glioblastoma in adults. **Metastatic Renal Cell Carcinoma (mRCC)** Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

Drug Name: Mvasi (bevacizumab-awwb), Zirabev (bevacizumab-bvzr)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent,

for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

Drug Name: Alymsys (bevacizumab-maly)

Metastatic Colorectal Cancer (mCRC) Indicated for the first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy. Bevacizumab, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Bevacizumab is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.

Off Label Uses: **Hepatocellular Carcinoma** Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial resection. [4, A] Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. [4, A]

Drug Name: Vegzelma (bevacizumab-adcd)

Metastatic Colorectal Cancer Indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC) in combination with intravenous fluorouracil-based chemotherapy. Vegzelma, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is also indicated for second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab-containing regimen. Limitation of use: Vegzelma is not indicated for adjuvant treatment of colon cancer.

Non-Squamous Non–Small Cell Lung Cancer (NSCLC) Indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma Indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC) Indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix Indicated for the treatment of persistent, recurrent, or metastatic cervical cancer when used in combination with paclitaxel and cisplatin or paclitaxel and topotecan.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer Indicated, in combination with carboplatin and paclitaxel, followed by Vegzelma as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection. Indicated, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens. Indicated, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Vegzelma as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Off Label Uses: Hepatocellular Carcinoma Indicated, in combination with atezolizumab, for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy. [4, A]

2 . Criteria

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
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 Requested 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 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Avastin, Mvasi, Zirabev, Alymsys, Vegzelma	
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

AND

2 - One of the following (applies to Avastin, Alymsys and Vegzelma only):

2.1 Trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Alymsys, Vegzelma	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Requested 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 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to both of the following:

- Mvasi
- Zirabev

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

3 . Endnotes

A. 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]

4 . References

1. Avastin Prescribing Information. Genentech Inc. South San Francisco, CA. September 2022.
2. Mvasi Prescribing Information. Amgen Inc. Thousand Oaks, CA. November 2021.
3. Zirabev Prescribing Information. Pfizer Inc. New York, NY. May 2021.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 21, 2023.
5. Alymsys Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. April 2022.
6. Vegzelma Prescribing Information. Celltrion USA, Inc. Jersey City, NJ. November 2022.

5 . Revision History

Date	Notes
10/2/2023	Streamlining all indications into one criteria bucket and added Vegzelma to NF criteria

Bortezomib

Prior Authorization Guideline

Guideline ID	GL-127096
Guideline Name	Bortezomib

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/2/2004
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 07/20/2022 ; 09/21/2022 ; 10/19/2022 ; 03/15/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Velcade (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of patients with mantle cell lymphoma.
Drug Name: Bortezomib (bortezomib)
Multiple Myeloma Indicated for the treatment of patients with multiple myeloma. **Mantle Cell Lymphoma** Indicated for the treatment of adult patients with mantle cell lymphoma.

2 . Criteria

Product Name: Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma [1, 2, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name: Brand Velcade, Generic bortezomib, Bortezomib	
Diagnosis	Mantle Cell Lymphoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mantle cell lymphoma [1, 3, 4, 5]

AND

2 - Trial and failure, contraindication or intolerance to generic bortezomib (Applies to Brand Velcade Only)

Product Name: Brand Velcade, Generic bortezomib, Bortezomib	
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. Velcade Prescribing Information. Millennium Pharmaceuticals, Inc. Cambridge, MA. November 2021.
2. Richardson PG, Sonneveld P, Schuster MW, et al. Assessment of Proteasome Inhibition for Extending Remissions (APEX) Investigators. Bortezomib or high-dose dexamethasone for relapsed multiple myeloma. N Engl J Med. 2005 Jun 16;352(24):2487-98.
3. National Cancer Institute. Adult Non-Hodgkin Lymphoma Treatment (PDQ). Available at: http://www.cancer.gov/cancertopics/pdq/treatment/adult-non-hodgkins/healthprofessional. Accessed May 12, 2022.
4. Fisher RI, Bernstein SH, Kahl BS, et al. Multicenter phase II study of bortezomib in patients with relapsed or refractory mantle cell lymphoma. J Clin Oncol.2006;24(30):4867-74.
5. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org. Accessed May 12, 2022.
6. Bortezomib Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2022.
7. Bortezomib Prescribing Information. Hospira, Inc.. Lake Forest, IL. December 2022.
8. Bortezomib Prescribing Information. Dr Reddy's Laboratories, Inc. Princeton, NJ. December 2022.
9. Bortezomib Prescribing Information. Hikma Pharmaceuticals USA, Inc. Berkeley Heights, NJ. November 2021.
10. Bortezomib Prescribing Information. Fosun Pharma USA. Princeton, NJ. August 2022.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Bosulif (bosutinib)

Prior Authorization Guideline

Guideline ID	GL-127559
Guideline Name	Bosulif (bosutinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	12/18/2019 ; 04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

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 - One of the following:

2.1 Trial and failure or intolerance to generic imatinib

OR

2.2 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 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.

4 . Revision History

Date	Notes
7/5/2023	Removed specialist requirement

Cablivi (caplacizumab-yhdp)

Prior Authorization Guideline

Guideline ID	GL-101562
Guideline Name	Cablivi (caplacizumab-yhdp)

Guideline Note:

Effective Date:	4/1/2022
P&T Approval Date:	4/17/2019
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 2/17/2022

1 . Indications

Drug Name: Cablivi (caplacizumab-yhdp)
Acquired Thrombotic 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 Thrombotic Thrombocytopenic Purpura (aTTP)
Approval Length	3 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acquired thrombotic 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

1. Cablivi Prescribing Information. Cambridge, MA. Genzyme Corporation. October 2021
2. Understanding TTP. https://www.understandingttp.com/patient/ttp-treatment/#overview-of-treatment. Accessed January 28, 2021.
3. FDA News Release: FDA approves first therapy for the treatment of adult patients with a rare blood clotting disorder. U.S. Food and Drug Administration; February 6, 2019. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm630851.htm. Accessed January 28, 2021.

5 . Revision History

Date	Notes
1/6/2022	2022 Annual Review - No changes to criteria, updated background in formation

Cabometyx (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-127632
Guideline Name	Cabometyx (cabozantinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/22/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/18/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

Product Name: Cabometyx	
Diagnosis	Hepatocellular Carcinoma (HCC)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma (HCC)

AND

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

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 - Patient is 12 years of age or older

AND

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

AND

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

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.

5 . Revision History

Date	Notes
7/5/2023	Updated criteria and removed specialist requirement

Caprelsa (vandetanib)

Prior Authorization Guideline

Guideline ID	GL-132293
Guideline Name	Caprelsa (vandetanib)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	7/12/2011
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

1 . Indications

Drug Name: Caprelsa (vandetanib)
Medullary Thyroid Cancer (MTC) Indicated for the treatment of symptomatic or progressive MTC in patients with unresectable locally advanced or metastatic disease. Use Caprelsa in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of Caprelsa.

2 . Criteria

Product Name: Caprelsa	
Approval Length	12 Months
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of one of the following:

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following:

- Patient has symptomatic disease
- Patient has progressive disease

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 therapy

3 . References

1. Caprelsa prescribing information. Genzyme Corporation. Cambridge, MA. December 2022.

4 . Revision History

Date	Notes
9/1/2023	Annual review: No criteria changes. Updated references.

Cayston (aztreonam for inhalation solution) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126313
Guideline Name	Cayston (aztreonam for inhalation solution) - PA, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	6/22/2010
P&T Revision Date:	06/17/2020 ; 01/20/2021 ; 06/16/2021 ; 12/15/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Cayston (aztreonam for inhalation solution)
Cystic Fibrosis Indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with Pseudomonas aeruginosa. Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Cayston and other antibacterial drugs, Cayston should be used only to treat patients with CF known to have Pseudomonas aeruginosa in the lungs.

2 . 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

AND

4 - Trial and failure, contraindication, or intolerance to TWO of the following:

- Bethkis* (tobramycin [300 mg/4 ml] inhalation solution)
- TOBI* (tobramycin [300 mg/5 ml] inhalation solution)
- Tobi Podhaler

Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Bethkis and brand TOBI

Product Name: Cayston	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
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 benefiting from treatment (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations)

Product Name: Cayston	
Approval Length	12 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to TWO of the following:

- generic tobramycin [300 mg/4 ml] inhalation solution
- generic tobramycin [300 mg/5 ml] inhalation solution

- Tobi Podhaler

3 . References

1. Cayston Prescribing Information. Gilead Sciences, Inc. Foster City, CA. November 2019.
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.

4 . Revision History

Date	Notes
6/7/2023	Annual review: No criteria changes.

Cholbam (cholic acid)

Prior Authorization Guideline

Guideline ID	GL-133020
Guideline Name	Cholbam (cholic acid)

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Cholbam (cholic acid)
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 PDs including Zellweger spectrum disorders have not been established. **Peroxisomal disorders including Zellweger spectrum disorders** 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.

2 . Criteria

Product Name: Cholbam

Diagnosis	Bile acid synthesis disorders
Approval Length	4 Months [F]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

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]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

2 - Prescribed by one of the following: [2,7,E]

- 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

Approval Criteria

1 - Diagnosis of a peroxisomal disorder based on one of the following: [2-5,8,C,D]

- An abnormal urinary bile acid analysis by mass spectrometry
- Molecular genetic testing consistent with the diagnosis

AND

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 - Patient demonstrates 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

1. Heubi JE, Setchell KD, Bove KE. Inborn errors of bile acid metabolism. Semin Liver Dis. 2007;27(3):282-94.
2. Cholbam Prescribing Information. Manchester Pharmaceuticals, Inc., San Diego, CA. May 2021.
3. Cholbam Product Monograph. Retrophin, Inc., 2015.
4. Bove KE, Heubi JE, Balistreri WF, Setchell KD. Bile acid synthetic defects and liver disease: a comprehensive review. Pediatr Dev Pathol. 2004;7(4):315-34.
5. Wanders RJA. Peroxisomal disorders. UpToDate web site. https://www.uptodate.com/contents/peroxisomal-disorders?search=bile%20acid%20synthesis%20disorder&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2#H53. Updated January 18, 2023. Accessed February 9, 2023.

6. Gonzales E, Gerhardt MF, Fabre M, et al. Oral cholic acid for hereditary defects of primary bile acid synthesis: a safe and effective long-term therapy. Gastroenterology. 2009;137(4):1310-1320.e1-3.
7. Per email with medical geneticist, June 10, 2015.
8. National Organization for Rare Disorders (NORD). Bile acid sythesis disorders. Available at: https://rarediseases.org/rare-diseases/bile-acid-synthesis-disorders/. Accessed February 9, 2023.

5 . Revision History

Date	Notes
9/13/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Cibinqo (abrocitinib)

Prior Authorization Guideline

Guideline ID	GL-121716
Guideline Name	Cibinqo (abrocitinib)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/16/2022
P&T Revision Date:	07/20/2022 ; 3/15/2023

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 the following FDA-approved atopic dermatitis therapies:

- 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

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:

- 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
	Betamethasone valerate	Cream, foam, lotion, ointment	0.1

Medium potency	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. January 2022.
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.

6 . Revision History

Date	Notes
2/26/2023	Updated indication and age criterion to include patients 12 years of a ge or older; background updates

Cimzia (certolizumab pegol)

Prior Authorization Guideline

Guideline ID	GL-132630
Guideline Name	Cimzia (certolizumab pegol)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/20/2008
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 04/19/2023

1 . Indications

Drug Name: Cimzia (certolizumab pegol)
Rheumatoid Arthritis (RA) Indicated for the treatment of adults with moderately to severely active rheumatoid arthritis. **Psoriatic Arthritis (PsA)** Indicated for the treatment of adult patients with active psoriatic arthritis (PsA). **Plaque Psoriasis (PsO)** Indicated for the treatment of adults with moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. **Ankylosing Spondylitis (AS)** Indicated for the treatment of adults with active ankylosing spondylitis. **Non-radiographic Axial Spondyloarthritis (nr-axSpA)** Indicated for the treatment of adults with active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. **Crohn’s Disease (CD)** 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.

2 . Criteria

Product Name: Cimzia	
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 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 [4, 5]:

- methotrexate
- leflunomide
- sulfasalazine

Product Name: Cimzia	
Diagnosis	Rheumatoid Arthritis (RA)
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, 5]:

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

Product Name: Cimzia	
Diagnosis	Psoriatic Arthritis
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 [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: Cimzia	
Diagnosis	Psoriatic 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, 6]:

- 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: Cimzia	
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 [8]:

- Greater than or equal to 3% body surface area involvment
- 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 [9]:

- 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: Cimzia	
Diagnosis	Plaque Psoriasis
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 ONE of the following [1, 8]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
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 nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

Product Name: Cimzia	
Diagnosis	Ankylosing Spondylitis
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, 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: Cimzia	
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, 7]

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 [7]

Product Name: Cimzia	
Diagnosis	Non-radiographic Axial Spondyloarthritis
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, 7]:

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

Product Name: Cimzia	
Diagnosis	Crohn's disease
Approval Length	16 Weeks [A]
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 [2, 3]:

- 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 (CDAI) greater than 220

AND

3 - Trial and failure, contraindication, or intolerance to ONE of the following conventional therapies [2, 3]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)

- Methotrexate

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Cimzia	
Diagnosis	Crohn’s disease
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]:

- 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 . 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. December 2022.
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. 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.

4. 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.
5. 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.
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. 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.
9. 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.

5 . Revision History

Date	Notes
9/5/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Cinqair (reslizumab)

Prior Authorization Guideline

Guideline ID	GL-133023
Guideline Name	Cinqair (reslizumab)

Guideline Note:

Effective Date:	1/1/2024

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

Approval Criteria

1 - Patient demonstrates 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 [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. 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 (2022 update). 2022 www.ginasthma.org. Accessed April 2023
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.

6 . Revision History

Date	Notes
9/13/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Prior Authorization Guideline

Guideline ID	GL-126095
Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/1/2006
P&T Revision Date:	01/15/2020 ; 04/15/2020 ; 08/13/2020 ; 02/18/2021 ; 04/21/2021 ; 12/15/2021 ; 04/20/2022 ; 11/17/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 6/21/2023

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 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 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.

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]

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: 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

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

AND

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

AND

3 - Patient is 2 years of age or older (applies to Leukine only)

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Bone Marrow/Stem Cell Transplant
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)

OR

1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis

OR

1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy

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 both of the following:

- Nivestym
- Zarxio

Product Name: Leukine	
Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

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	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

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

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen

Diagnosis	Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy
Approval Length	3 months or duration of therapy [C]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acute myeloid leukemia (AML) [A]

AND

2 - Patient has completed induction or consolidation chemotherapy [27]

AND

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

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Fulphila, Fylnetra, Granix, Leukine (Off-Label), Neulasta/Neulasta Onpro, Releuko, Neupogen, Nivestym, Nyvepria, Stimufend, Udenyca, Zarxio, or Ziextenzo	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

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 - One of the following:

3.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Udenyca	
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 - One of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

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, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Prior Authorization

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 - Trial and failure or intolerance to ONE of the following:

- Neulasta/Neulasta Onpro
- Ziextenzo

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
- Ziextenzo

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	3 Months of duration of therapy
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, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is 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 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):

- Nivestym
- Zarxio

OR

5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Udenyca	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months of duration of therapy
Guideline Type	Non Formulary

Approval Criteria

1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, l]

AND

2 - Diagnosis of febrile neutropenia (FN)

AND

3 - Patient is 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 both of the following (applies to Neupogen and Granix only):

- Nivestym
- Zarxio

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, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

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 severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm^3) [16]

AND

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

AND

3 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [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 both of the following:

- Nivestym

- Zarxio

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)
Approval Length	1 Months [N]
Guideline Type	Prior Authorization

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 Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

OR

3.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, and Stimufend, Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Udenyca	
Diagnosis	Acute Radiation Syndrome (ARS)
Approval Length	1 Months [N]
Guideline Type	Non Formulary

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 both of the following (applies to Neupogen only):

- Nivestym
- Zarxio

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, Nyvepria, and Udenyca only):

- Neulasta/Neulasta Onpro
- Ziextenzo

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

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

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

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Non Formulary

Approval Criteria

1 - Patient is infected with HIV virus [11- 13]

AND

2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]

AND

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

- Hematologist/oncologist
- Infectious disease specialist

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

Product Name: Neupogen, Nivestym, Releuko, Zarxio	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
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 Patient is 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 Patient has neutropenia (absolute neutrophil count [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 Patient is experiencing 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 Human Immunodeficiency Virus (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 both of the following (applies to Neupogen and Releuko only):

- Nivestym
- Zarxio

Product Name: Neupogen	
Diagnosis	Hepatitis-C Treatment Related Neutropenia (Off-Label)
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 Patient is 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 Patient has neutropenia (absolute neutrophil count [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 Patient is experiencing 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 Human Immunodeficiency Virus (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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:

- Nivestym
- Zarxio

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	• Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	• 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]	• Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	• FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	• TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	• Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubivin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	• Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	• 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	• Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma	• DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)

Ovarian Cancer	• Topotecan • Docetaxel
Pancreatic Cancer	• FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	• MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	• Topotecan
Testicular Cancer	• 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	• Gemcitabine/docetaxel
Breast Cancer	• Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	• Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	• FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL)[26]	• 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	• Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel

	• Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	• Carboplatin/docetaxel
Prostate Cancer	• Cabazitaxel
Testicular Cancer	• Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	• Irinotecan/cisplatin • Epirubicin/cisplatin/5-flurouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	• Etoposide/carboplatin
Uterine Cancer	• 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/mm^3. [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/mm^3) 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/mm^3) [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, tbo-filgrastim, 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 10^9 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]

5 . References

1. Neulasta Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
2. Neupogen Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2021.
3. Leukine Prescribing Information. sanofi-aventis U.S. LLC. Bridgewater, NJ. May 2022.
4. Sulkowski M. Managing the hematologic complications of interferon/ribavirin. Clinical Care Options for Hepatitis Annual Update. Milford, MA: IMedoptions, 2003:101-102.
5. Soza A, Everhart JE, Gharny MG, et al. Neutropenia during combination therapy of interferon alfa and ribavirin for chronic hepatitis C. Hepatol. 2002;36:1273-1279.
6. Van Thiel DH, Faruki H. Combination treatment of advanced HCV associated liver disease with interferon and G-CSF. Hepatogastroenterol.1995;42:907-912.

7. Carreno V, Parra A, Navas S, Quiroga J. Granulocyte macrophage colony stimulating factors as adjuvant therapy for interferon alpha treatment of chronic hepatitis C. Cytokine. 1996;8:318-322.
8. Shiffman M, Hofmann, Luketic VA, Sanyal AJ. Use of granulocyte macrophage colony stimulating factor alone or in combination with interferon-alpha-2b for treatment of chronic hepatitis C. J Hepatol.1998;28:382-389.
9. Farmer D, Collantes R, Makay S, et al. Filgrastim for the neutropenia associated with combination therapy in chronic hepatitis C. Gastroenterol. 2005;128(4, Suppl2):a-725.
10. Stein DF, McKenzie SD. Peg-interferon alfa-2b and ribavirin in treatment naïve African American patients infected with HCV genotype 1. Hepatol.2003;38(4):642A.
11. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 3, 2020.
12. Hermans P, Rozenbaum W, Jou A, et al. Filgrastim to treat neutropenia and support myelosuppressive medication dosing in HIV infections. G-CSF 92105 Study Group. AIDS 1996;10:1627-33.
13. Kuritzkes, DR, Parenti D, Ward DJ, et al. Filgrastim prevents severe neutropenia and reduces infective morbidity in patients with advanced HIV infection; results of a randomized, multicenter, controlled trial. AIDS 1998;12:65-74.
14. Levine AM, Karim R, Mack W, et al. Neutropenia in human immunodeficiency virus infection: data from the women's interagency HIV study. Arch Intern Med. 2006;166:405-410.
15. Centers for Disease Control and Prevention. Guidelines for Preventing Opportunistic Infections Among HIV-Infected Persons – 2002 Recommendations of the U.S. Public Health Service and the Infectious Disease Society of America. MMWR 2002;51(No. RR-8):1-52.
16. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors. v.2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed March 29, 2023.
17. Smith TJ, Khatcheressian J, Lyman GH, et al. 2006 update of recommendations for the use of white blood cell growth factors: an evidence-based clinical practice guideline. J Clin Oncol. 2006;24:3187-205.
18. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast cancer. v.2.2022 Available at: http://www.nccn.org/professionals/physician_gls/PDF/breast.pdf. Accessed March 29, 2022.
19. Citron ML, Berry DA, Cirrincione C, et al. Randomized trial of dose-dense versus conventionally scheduled and sequential versus concurrent combination chemotherapy as postoperative adjuvant treatment of node-positive primary breast cancer: first report of Intergroup Trial C9741/Cancer and Leukemia Group B trial. J Clin Oncol. 2003;21(8):1431-9.
20. Ziextenzo Prescribing Information. Sandoz Inc. Princeton, NJ. March 2021.
21. Pegasys Prescribing Information. Roche Pharmaceuticals. San Francisco, CA. March 2021.
22. PegIntron Prescribing Information. Schering Corporation. Kenilworth, NJ. August 2019.
23. American Gastroenterological Association. Medical Position Statement on the Management of Hepatitis C. Gastroenterol 2006;130:225-30.
24. Ghany MG, Strader DB, Thomas DL, Seeff LB; American Association for the Study of Liver Diseases. Diagnosis, management, and treatment of hepatitis C: an update. Hepatology. 2009;49(4):1335-74.

25. Hudis CA, Schmitz. Dose-dense chemotherapy in breast cancer and lymphoma. Seminar in Oncol. 2004;31(Suppl 8):19-23.
26. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphoma. v.1.2016. Available at: http://www.nccn.org/professionals/physician_gls/PDF/nhl.pdf Accessed November 12, 2015.
27. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.1.2018. Available at: http://www.nccn.org/professionals/physician_gls/PDF/aml.pdf Accessed June 5, 2018.
28. Granix Prescribing Information. Cephalon, Inc. North Wales, PA. October 2019.
29. Zarxio Prescribing Information. Sandoz Inc. Princeton, NJ. July 2021.
30. Fulphila Prescribing Information. Mylan. Rockford, IL. March 2021.
31. Nivestym Prescribing Information. Pfizer, Inc. New York, NY. May 2021.
32. Udenyca Prescribing Information. Coherus BioSciences Inc. Redwood City, CA. March 2023.
33. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed March 3, 2020.
34. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of WBC growth factors: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2015;33(28):3199-3212.
35. Per clinical consult with hematologist/oncologist. December 20, 2018.
36. Dainiak N, Gent RN, Carr Z, et al. First global consensus for evidence-based management of the hematopoietic syndrome resulting from exposure to ionizing radiation. Disaster Med Public Health Prep. 2011;5(3):202.
37. Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed March 3, 2020.
38. Nyvepria Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. April 2021.
39. Releuko Prescribing Information. Kashiv BioSciences, LLC. Piscataway, NJ. February 2022.
40. Fylnetra Prescribing Information. Kashiv BioSciences, LLC. Piscataway, NJ. May 2022.
41. Rolvedon Prescribing Information.Spectrum Pharmaceuticals, Inc.Irvine, CA. September 2022.
42. Stimufend Prescribing Information.Fresenius Kabi USA, LLC. Lake Zurich, Illinois. September 2022.

6 . Revision History

Date	Notes
5/26/2023	Addition of Udenyca auto-injector

Cometriq (cabozantinib)

Prior Authorization Guideline

Guideline ID	GL-134136
Guideline Name	Cometriq (cabozantinib)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	08/16/2018 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Cometriq (cabozantinib)
Medullary thyroid cancer Indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer (MTC). **Off Label Uses: Non-small cell lung cancer** Has activity against RET gene rearrangements in non-small cell lung cancer (NSCLC). [3]

2 . 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]

- Metastatic medullary thyroid cancer (MTC)
- Unresectable locally advanced MTC

AND

2 - One of the following: [2]

- Patient has symptomatic disease
- Patient has progressive disease

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 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]

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 therapy

3 . 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]

4 . References

1. Cometriq prescribing information. Exelixis, Inc. Alameda, CA. February 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Thyroid Carcinoma. v4.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed on October 2, 2023.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Non-Small Cell Lung Cancer v3.2023. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed on October 2, 2023.

5 . Revision History

Date	Notes
10/2/2023	Annual review: No criteria changes. Updated references.

Copper Chelating Agents - PA, NF

Prior Authorization Guideline

Guideline ID	GL-135933
Guideline Name	Copper Chelating Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/20/2014
P&T Revision Date:	10/16/2019 ; 12/18/2019 ; 04/15/2020 ; 09/16/2020 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 04/15/2023 ; 06/21/2023 ; 08/20/2023 ; 08/20/2023 ; 11/16/2023

1 . Indications

Drug Name: Cuprimine (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, generic penicillamine	
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, or intolerance to Depen (penicillamine) tablets

AND

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

- Gastroenterologist

- Hepatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cystinuria

AND

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

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Trial and failure, or intolerance to Depen (penicillamine) tablets

AND

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

- Nephrologist
- Urologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

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 Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Brand Cuprimine, 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 Cuprimine, generic penicillamine

Diagnosis	Wilson's Disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

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

- Gastroenterologist
- Hepatologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Cystinuria
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of cystinuria

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to both of the following:

- Urinary alkalinization therapy [4]
- Thiola (tiopronin) [A]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

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

- Nephrologist
- Urologist

Product Name: Brand Cuprimine, generic penicillamine	
Diagnosis	Rheumatoid Arthritis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to Depen (penicillamine) tablets

AND

4 - Prescribed by or in consultation with a rheumatologist

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For Brand Syprine and Cuvrior, trial and failure, or intolerance to generic trientine

Product Name: Cuvrior

Diagnosis	Wilson's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Depen (penicillamine) tablets

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic trientine

AND

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

- Gastroenterologist
- Hepatologist

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. Orphalan SA. Chicago, IL. May 2022.

5 . Revision History

Date	Notes
11/7/2023	Add generic trientine 500mg capsule as target to guideline.

Prior Authorization Guideline

Guideline ID	GL-136071
Guideline Name	Cosentyx (secukinumab) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/18/2015
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 08/13/2020 ; 09/16/2020 ; 07/21/2021 ; 08/19/2021 ; 10/20/2021 ; 01/19/2022 ; 03/16/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022 ; 07/19/2023 ; 08/17/2023 ; 12/13/2023

1 . Indications

Drug Name: Cosentyx SC (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.

Hidradenitis Suppurativa (HS) Indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa (HS).
Drug Name: Cosentyx IV (secukinumab)
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: Cosentyx SC	
Diagnosis	Plaque Psoriasis (PsO)
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 - 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 [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 SC	
Diagnosis	Plaque Psoriasis (PsO)
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 ONE of the following [1-3]:

- Reduction the BSA involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

AND

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 SC	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - 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 IV & SC

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]:

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

AND

3 - One of the following:

- Cosentyx SC: Patient is 2 years of age or older
- Cosentyx IV: Patient is 18 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 IV & SC

Diagnosis	Psoriatic Arthritis (PsA)
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, pruritus, inflammation) from baseline
- Reduction in the BSA involvement from baseline

Product Name: Cosentyx IV & SC	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 - One of the following:

- Cosentyx SC: Patient is 2 years of age or older
- Cosentyx IV: Patient is 18 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 BSA involvement from baseline

Product Name: Cosentyx IV & SC	
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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Cosentyx IV & SC	
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 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 IV & SC	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Cosentyx IV & SC	
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, 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 IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
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 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 IV & SC	
Diagnosis	Non-radiographic Axial Spondyloarthritis (nr-axSpA)
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 SC	
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 SC	
Diagnosis	Enthesitis-Related Arthritis (ERA)
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, 6]:

- 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 SC	
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]

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa

AND

2 - Prescribed by or in consultation with a dermatologist

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 Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz

OR

3.2 Both of the following:

3.2.1 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

3.2.2 Documentation of positive clinical response to therapy

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Cosentyx SC	
Diagnosis	Hidradenitis Suppurativa (HS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderate to severe hidradenitis suppurativa

AND

2 - Prescribed by or in consultation with a dermatologist

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 Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz

OR

3.2 Both of the following:

3.2.1 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

3.2.2 Documentation of positive clinical response to therapy

3 . References

1. Cosentyx prescribing information. Novartis Pharmaceuticals Corp. East Hanover, NJ. October 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.

4 . Revision History

Date	Notes
11/30/2023	Addition of Cosentyx IV to existing PsA, AS, and nr-axSpA criteria; a ddition of criteria for hidradenitis suppurativa (HS)

Cotellic (cobimetinib)

Prior Authorization Guideline

Guideline ID	GL-126138
Guideline Name	Cotellic (cobimetinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	07/17/2019 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 12/14/2022 ; 7/19/2023

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.

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/ucm301431.htm. Accessed May 30, 2023.

5 . Revision History

Date	Notes
7/6/2023	Annual review: Updated criteria and background.

Dacogen (decitabine)/Inqovi (decitabine and cedazuridine) tablets - PA, NF

Prior Authorization Guideline

Guideline ID	GL-128518
Guideline Name	Dacogen (decitabine)/Inqovi (decitabine and cedazuridine) tablets - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	12/2/2006
P&T Revision Date:	09/18/2019 ; 08/13/2020 ; 10/21/2020 ; 08/19/2021 ; 01/19/2022 ; 08/18/2022 ; 8/17/2023

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
Approval Criteria **1** - Diagnosis of myelodysplastic syndrome	

Product Name: Inqovi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of myelodysplastic syndrome **AND** **2** - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)	

Product Name: Brand Dacogen, Generic decitabine, Inqovi	
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: Inqovi	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of myelodysplastic syndrome

AND

2 - Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS)

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.

4 . Revision History

Date	Notes
8/8/2023	Annual Review

Daraprim (pyrimethamine)

Prior Authorization Guideline

Guideline ID	GL-125293
Guideline Name	Daraprim (pyrimethamine)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	10/13/2015
P&T Revision Date:	05/14/2020 ; 06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

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

Approval Criteria

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]

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. Vyera 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/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/treatment-hiv-associated. Accessed May 5, 2023.
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, 2023.
4. Parasites - Toxoplasmosis (Toxoplasma infection). https://www.cdc.gov/parasites/toxoplasmosis/health_professionals/index.html#tx. Accessed May 5, 2023.
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, 2023.

5 . Revision History

Date	Notes
5/31/2023	Annual Review

Prior Authorization Guideline

Guideline ID	GL-126542
Guideline Name	Darzalex (daratumumab), Darzalex Faspro (daratumumab and hyaluronidase-fihj) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 03/18/2020 ; 05/14/2020 ; 07/15/2020 ; 10/21/2020 ; 03/17/2021 ; 09/15/2021 ; 12/15/2021 ; 02/17/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Darzalex (daratumumab)
Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent. **Multiple Myeloma - Combination therapy** Indicated in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy. **Multiple Myeloma - Combination therapy** Indicated in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy. **Multiple Myeloma - Combination therapy** Indicated in combination pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant.

Drug Name: Darzalex Faspro (daratumumab and hyaluronidase-fihj)

Multiple Myeloma - Monotherapy Indicated as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.

Multiple Myeloma - Combination Indicated in combination with lenalidomide and dexamethasone or bortezomib and dexamethasone in patients who have received at least one prior therapy.

Multiple Myeloma - Combination Indicated in combination with pomalidomide and dexamethasone in patients who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.

Multiple Myeloma - Combination Multiple Myeloma - Combination therapy Indicated in combination with carfilzomib and dexamethasone in patients who have received one to three prior lines of therapy.

Newly Diagnosed Multiple Myeloma Indicated in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant

Newly Diagnosed Multiple Myeloma Indicated in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant

Light Chain (AL) Amyloidosis Indicated in combination with bortezomib, cyclophosphamide and dexamethasone in newly diagnosed patients. 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: Darzalex	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex Faspro	
Diagnosis	Relapsed/Refractory Multiple Myeloma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

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

2.1 Both of the following:

2.1.1 Used as monotherapy

AND

2.1.2 One of the following:

2.1.2.1 Patient has received at least three prior treatment regimens which included both of the following:

- Proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])
- Immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid])

OR

2.1.2.2 Patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent

OR

2.2 Both of the following:

2.2.1 Used in combination with one of the following treatment regimens:

- lenalidomide and dexamethasone
- bortezomib and dexamethasone
- carfilzomib and dexamethasone

AND

2.2.2 Patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro]), lenalidomide [Revlimid], thalidomide [Thalomid]) [2]

OR

2.3 Both of the following:

2.3.1 Used in combination with both of the following:

- pomalidomide
- dexamethasone

AND

2.3.2 Patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis])

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Newly Diagnosed Multiple Myeloma
Approval Length	12 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Newly diagnosed multiple myeloma

AND

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

2.1 Both of the following:

2.1.1 Patient is ineligible for autologous stem cell transplant

AND

2.1.2 One of the following:

2.1.2.1 Used in the combination with all of the following:

- bortezomib
- melphalan
- prednisone

OR

2.1.2.2 Both of the following:

- lenalidomide
- dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient is eligible for autologous stem cell transplant

AND

2.2.2 Used in combination with all of the following:

- bortezomib
- thalidomide
- dexamethasone

Product Name: Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name: Darzalex Faspro	
Diagnosis	Light Chain Amyloidosis
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Newly diagnosed light chain (AL) amyloidosis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with ALL of the following:

- Bortezomib
- Cyclophosphamide
- Dexamethasone

AND

3 - All of the following

- Patient does not have New York Heart Association (NYHA) Class IIIB disease
- Patient does not have New York Heart Association (NYHA) Class IV disease
- Patient does not have Mayo Stage IIIB disease

Product Name: Darzalex, Darzalex Faspro	
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. Darzalex Prescribing Information. Janssen Biotech, Inc. Horsham, PA. January 2023.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v4.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed December 2021.
3. Darzalex Faspro Prescribing Information. Janssen Biotech, Inc. Horsham, PA. December 2022

4 . Revision History

Date	Notes
7/18/2023	Removed oncologist specialist requirement

Diacomit (stiripentol)

Prior Authorization Guideline

Guideline ID	GL-131358
Guideline Name	Diacomit (stiripentol)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 09/21/2022 ; 05/18/2023 ; 5/18/2023

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 - Patient demonstrates positive clinical response to therapy

AND

2 - Used in combination with clobazam

3 . References

1. Diacomit Prescribing Information. Biocodex. Gentilly, France. July 2022.

4 . Revision History

Date	Notes
8/22/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Dupixent (dupilumab)

Prior Authorization Guideline

Guideline ID	GL-131363
Guideline Name	Dupixent (dupilumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 02/13/2020 ; 07/15/2020 ; 03/17/2021 ; 08/19/2021 ; 11/18/2021 ; 12/15/2021 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 07/20/2022 ; 11/17/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Dupixent (dupilumab)
Atopic Dermatitis (AD) 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. **Asthma** Indicated as an add-on maintenance treatment of adult and pediatric 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. **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). **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).

Prurigo Nodularis (PN) Indicated for the treatment of adult patients with prurigo nodularis (PN).

2 . Criteria

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
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 - 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]:

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

AND

4 - Patient is 6 months of age or older

AND

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

- Dermatologist
- Allergist/Immunologist

Notes	*Product may require step therapy

Product Name: Dupixent	
Diagnosis	Atopic Dermatitis
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- Reduction in BSA involvement from baseline
- Reduction in SCORAD index value from baseline [A]

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 (pre-treatment) 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) (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

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

Approval Criteria

1 - Patient demonstrates 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
Approval Length	6 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe asthma

AND

2 - Patient is 6 years of age or older

AND

3 - Patient is currently dependent on oral corticosteroids for the treatment of asthma

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 [6]:

- 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])

AND

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

- Pulmonologist
- Allergist/Immunologist

Product Name: Dupixent	
Diagnosis	Oral Corticosteroid Dependent Asthma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., reduction in exacerbations, improvement in FEV1, reduction in oral corticosteroid dose)

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	Chronic rhinosinusitis with nasal polyposis (CRSwNP)
Approval Length	12 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 - Used in combination with another agent for CRSwNP [F]

AND

4 - 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

Approval Criteria

1 - Patient demonstrates 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])

AND

2 - Used in combination with another agent for CRSwNP [F]

AND

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

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

Product Name: Dupixent	
Diagnosis	Eosinophilic Esophagitis (EoE)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of eosinophilic esophagitis (EoE)

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

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline [1, 13-15]:

- 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

Approval Criteria

1 - Diagnosis of prurigo nodularis (PN)

AND

2 - Patient has at least 20 nodular lesions

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 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- 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

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 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.
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. 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 March 2, 2021.
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.
5. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N Engl J Med. 2018; 378(26):2486-96.
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.

9. 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.
10. 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.
11. 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.
12. 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.
13. Gonsalves NP, Aceves SS. Diagnosis and treatment of eosinophilic esophagitis. J Allergy Clin Immunol. 2020;145(1):1-7.
14. Hirano I, Chan ES, Rank MA, et al. AGA Institute and the Joint Task Force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. Gastroenterology. 2020;158:1776-86.
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.

6 . Revision History

Date	Notes
8/22/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Elaprase (idursulfase)

Prior Authorization Guideline

Guideline ID	GL-127547
Guideline Name	Elaprase (idursulfase)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/30/2004
P&T Revision Date:	07/08/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Elaprase (idursulfase) [1]
Hunter Syndrome Is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Elaprase have not been established in pediatric patients less than 16 months of age.

2 . Criteria

Product Name: Elaprase (idursulfase)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of Hunter syndrome (Mucopolysaccharidosis II, MPS II)	

Product Name: Elaprase (idursulfase)	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria **1** - Documentation of positive clinical response to therapy	

3 . References

1. Elaprase Prescribing Information. Takeda Pharmaceuticals U.S.A., Inc. Lexington, MA. October 2021.

4 . Revision History

Date	Notes
7/5/2023	Annual review, changed initial auth to 12 months, added 24 month re auth.

Emflaza (deflazacort) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-124021
Guideline Name	Emflaza (deflazacort) - PA, NF

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	4/26/2017
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 08/19/2021 ; 05/19/2022 ; 5/18/2023

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

Approval Criteria

1 - Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength)

AND

2 - Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

Product Name: Emflaza	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of Duchenne muscular dystrophy (DMD)

AND

2 - Patient has received genetic testing for a mutation of the dystrophin gene [A, 2]

AND

3 - Submission of medical records (e.g., chart notes, laboratory values) documenting 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

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.

5 . Revision History

Date	Notes
5/4/2023	Annual review: Updated Non Formulary criteria and background.

Empliciti (elotuzumab)

Prior Authorization Guideline

Guideline ID	GL-127102
Guideline Name	Empliciti (elotuzumab)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 02/18/2021 ; 02/17/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Empliciti (elotuzumab)
Multiple myeloma Indicated in combination with lenalidomide and dexamethasone for the treatment of adult patient with multiple myeloma who have received one to three prior therapies. **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: Empliciti	
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has received at least one prior therapy for multiple myeloma [e.g., Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)]

AND

2.1.2 Used in combination with both of the following: [2]

- Revlimid (lenalidomide)*
- Dexamethasone

OR

2.2 Both of the following:

2.2.1 Patient has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor

AND

2.2.2 Used in combination with both of the following: [2]

- Pomalyst (pomalidomide)**
- dexamethasone

Notes	*This product may require prior authorization.

Product Name: Empliciti	
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. Empliciti Prescribing Information. Bristol-Myers Squibb Company. Princeton, NJ. March 2022.
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Multiple Myeloma v. 2.2020. Available by subscription at: http://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf. Accessed February 27, 2023.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Enbrel (etanercept)

Prior Authorization Guideline

Guideline ID	GL-136967
Guideline Name	Enbrel (etanercept)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/15/2005
P&T Revision Date:	08/15/2019 ; 09/18/2019 ; 10/16/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 10/19/2022 ; 04/19/2023 ; 04/19/2023 ; 12/13/2023

1 . Indications

Drug Name: Enbrel (etanercept)
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. **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. **Psoriatic Arthritis (PsA)** Indicated for reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in adult patients with psoriatic arthritis. Enbrel can be used with or without MTX. Also indicated for the treatment of active juvenile psoriatic arthritis (JPsA) in pediatric patients 2 years of age and older. **Plaque Psoriasis (PsO)** Indicated for the treatment of patients 4 years or older with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or

phototherapy.

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

2 . Criteria

Product Name: Enbrel	
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

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

Product Name: Enbrel	
Diagnosis	Rheumatoid Arthritis (RA)
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

Product Name: Enbrel	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

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

Product Name: Enbrel	
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

Product Name: Enbrel	
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 [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

Product Name: Enbrel	
Diagnosis	Psoriatic Arthritis (PsA)
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, 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

Product Name: Enbrel	
Diagnosis	Plaque Psoriasis (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe chronic plaque psoriasis

AND

2 - One of the following [6]:

- 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 (PsO)
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 ONE of the following [1, 6]:

- 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 - Patient demonstrates 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. October 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. 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.

4 . Revision History

Date	Notes
11/30/2023	Updated PsA indication to include pediatric patients; no criteria chan ges

Enhertu (fam-trastuzumab deruxtecan-nxki)

Prior Authorization Guideline

Guideline ID	GL-126832
Guideline Name	Enhertu (fam-trastuzumab deruxtecan-nxki)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/13/2020
P&T Revision Date:	02/18/2021 ; 03/17/2021 ; 02/17/2022 ; 06/15/2022 ; 10/19/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Enhertu (fam-trastuzumab deruxtecan-nxki)
Breast cancer Indicated for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2) - positive breast cancer who have received a prior anti-HER2-based regimen in either the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy. **Breast cancer** Indicated for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy. **Gastric Cancer** Indicated for the treatment of adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen. **Non-Small Cell Lung Cancer** Indicated for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior

systemic therapy. This indication is approved under accelerated approval based on objective 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.

2 . Criteria

Product Name: Enhertu	
Diagnosis	Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gastric or gastroesophageal junction (GEJ) adenocarcinoma

AND

2 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

3 - Disease is ONE of the following:

- Locally advanced
- Metastatic

AND

4 - Patient has received a prior trastuzumab-based regimen (e.g., Kanjinti, Trazimera)

Product Name: Enhertu

Diagnosis	Breast Cancer
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:

- Unresectable
- Metastatic

AND

3 - One of the following:

3.1 Both of the following:

- Disease is human epidermal growth factor receptor 2 (HER2)-positive
- Patient has received one prior anti-HER2-based regimens (e.g. trastuzumab + pertuzumab + docetaxel, ado-trastuzumab emtansine) [2] [3]

OR

3.2 Both of the following:

- Disease is HER2-low
- Patient has received a prior chemotherapy

Product Name: Enhertu	
Diagnosis	Non-Small Cell Lung Cancer

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:

- Unresectable
- Metastatic

AND

3 - Patient has known active human epidermal growth factor receptor 2 (HER2) ERBB2 mutations 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 a prior systemic therapy (e.g., chemotherapy)

Product Name: Enhertu	
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. Enhertu Prescribing Information. Daiichi Sankyo, Inc., Basking Ridge, NJ. August 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 22, 2022.
3. Modi S, Saura C, Yamashita T, et al. Trastuzumab Deruxtecan in previously treated HER2-positive breast cancer. N Engl J Med, 2019 December.
4. Shitara K, Bang YJ, Iwasa S, et al. DESTINY-Gastric01 Investigators. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Gastric Cancer. N Engl J Med. 2020 June.

4 . Revision History

Date	Notes
6/22/2023	Removed specialist requirement

Epclusa (sofosbuvir/velpatasvir) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126030
Guideline Name	Epclusa (sofosbuvir/velpatasvir) - PA, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	6/22/2016
P&T Revision Date:	05/14/2020 ; 12/16/2020 ; 06/16/2021 ; 11/18/2021 ; 01/19/2022 ; 06/15/2022 ; 06/15/2022 ; 6/21/2023

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

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 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 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.

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 - Epclusa 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 Epclusa, 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
Approval Length	24 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 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

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 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 - 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
Approval Length	24 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 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. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 14, 2023.

4 . Revision History

Date	Notes
6/6/2023	Annual review - no criteria changes; background updates

Epidiolex (cannabidiol)

Prior Authorization Guideline

Guideline ID	GL-134061
Guideline Name	Epidiolex (cannabidiol)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/16/2018
P&T Revision Date:	05/14/2020 ; 10/21/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

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

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)
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Patient demonstrates positive clinical response to therapy	

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.

5 . Revision History

Date	Notes

9/29/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Erivedge (vismodegib)

Prior Authorization Guideline

Guideline ID	GL-132168
Guideline Name	Erivedge (vismodegib)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	4/10/2012
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

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

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..

4 . Revision History

Date	Notes
8/31/2023	Annual Review - No criteria changes

Prior Authorization Guideline

Guideline ID	GL-135161
Guideline Name	Erythropoietic Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/17/2000
P&T Revision Date:	11/14/2019 ; 04/15/2020 ; 11/12/2020 ; 01/20/2021 ; 11/18/2021 ; 12/15/2021 ; 02/17/2022 ; 11/17/2022 ; 06/21/2023 ; 11/16/2023

1 . Indications

Drug Name: Aranesp (darbepoetin alfa)
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. **Anemia Due to Chemotherapy in Patients with Cancer** 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. **Off Label Uses: Anemia in patients with Myelodysplastic Syndrome (MDS)** Has 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 Patients with HIV-infection** Indicated for the treatment of anemia due to zidovudine administered at less than or equal to 4200 mg/week in patients with HIV-infection 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. Epoetin alfa is not indicated for patients who are willing to donate autologous blood preoperatively. 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 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. Limitations of use: 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

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

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]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/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

AND

5 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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) less than 30%
- Hemoglobin (Hgb) less than 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, Retacrit)

AND

3.2.4 Patient is converting to Mircera from another ESA (e.g., Aranesp, Retacrit)

AND

4 - History of use or unavailability of both of the following: [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (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, 31, 33]

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 Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chronic Kidney Disease (CKD)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic kidney disease (CKD)

AND

2 - Verification of iron evaluation for adequate iron stores^ [A, J]

AND

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]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/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

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp

• Retacrit or Procrit	
Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
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) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 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:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Patients with HIV-infection
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: [2, 3, 33]

- 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

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 1g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Patients with HIV-infection
Approval Length	6 month(s)
Guideline Type	Non Formulary

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) less than 12 g/dL [11, 25-28, K]
- Hematocrit (Hct) less than 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:

- Patient is receiving zidovudine therapy [2-3, 33]
- Diagnosis of HIV infection [off-label] [5, 11, 24-28]

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

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]

- Hemoglobin (Hgb) less than 10 g/dL
- Hematocrit (Hct) less than 30% [10, 18-19]

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

AND

3 - Patient is receiving chemotherapy [D]

Product Name: Epogen, Procrit	
Diagnosis	Anemia Due to Chemotherapy in Patients with Cancer
Approval Length	3 Months [C]
Guideline Type	Non Formulary

Approval Criteria

1 - Verification that other causes of anemia have been ruled out [1-3, 33, M]

AND

2 - Verification of anemia as defined by one of the following laboratory values collected within the prior two weeks of the request: [1-3, 33]

- Hematocrit (Hct) less than 30%
- Hemoglobin (Hgb) less than 10 g/dL [N]

AND

3 - Verification of iron evaluation for adequate iron stores ^ [1-3, 8, 33, G]

AND

4 - Verification that the cancer is a non-myeloid malignancy [1-3, 33, F]

AND

5 - Patient is receiving chemotherapy [1-3, 33, D]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit

Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Prior Authorization

Approval Criteria

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]

AND

6 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit

Diagnosis	Preoperative use for reduction of allogeneic blood transfusion in patients undergoing surgery
Approval Length	1 month [2]
Guideline Type	Non Formulary

Approval Criteria

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]

AND

6 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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 erythropoietin 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]

AND

4 - History of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (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]

- 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 1.5 g/dL from pre-treatment level

Product Name: Epogen, Procrit	
Diagnosis	Anemia in Myelodysplastic Syndrome (MDS) patients [off-label] [4-6, 20]
Approval Length	3 months [I]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Myelodysplastic Syndrome (MDS) [4]

AND

2 - One of the following: [4]

- Serum erythropoietin 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]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of both of the following (applies to Epogen only): [O]

- Aranesp
- Retacrit or Procrit

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

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) less than 36%
- Hemoglobin (Hgb) less than 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

AND

5 - History of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Epogen, Procrit, or Retacrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label]
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

Product Name: Epogen, Procrit	
Diagnosis	Anemia in HCV-infected patients due to ribavirin in combination with interferon or peg-interferon [off-label] [6]
Approval Length	3 month(s)
Guideline Type	Non Formulary

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) less than 36%
- Hemoglobin (Hgb) less than 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

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming history of use or unavailability of Retacrit or Procrit (applies to Epogen only) [O]

Notes	^Authorization will be given if physician is aware of iron deficiency and is taking steps to replenish iron stores.

Product Name: Aranesp, Epogen, Mircera, Procrit, or Retacrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Prior Authorization

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND **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]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clin ical pharmacist

Product Name: Epogen, Procrit	
Diagnosis	Other Off-Label Uses
Guideline Type	Non Formulary

Approval Criteria

1 - Off-label guideline approval criteria have been met*

AND

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]

Notes	*Off-label requests will be evaluated on a case-by-case basis by a clin ical pharmacist

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 hemoglobin 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 rivabirin in anemic patients with chronic hepatitis C virus in patients with a baseline hemoglobin of 12 g/dL or less. [20]

4 . References

1. Aranesp prescribing information. Amgen Inc. Thousand Oaks, CA. January 2019.
2. Epogen prescribing information. Amgen Inc. Thousand Oaks, CA. July 2018.
3. Procrit prescribing information. Amgen Inc. Thousand Oaks, CA. July 2018.
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Myelodysplastic Syndromes v.2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed October 27, 2023.
5. AHFS Drug Information website. Available at: http://online.lexi.com/lco/action/doc/retrieve/docid/complete_ashp/414035. Accessed October 31, 2022.
6. Micromedex Healthcare Series. Thomson Micromedex. Accessed October 31, 2022.

7. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279-335.
8. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Hematopoietic Growth Factors v1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf. Accessed October 31, 2022.
9. Eschbach JW, Abdulhadi MH, Browne JE, et al. Recombinant human erythropoietin in anemic patients with end-stage renal disease. Ann Intern Med 1989;111:992-1000.
10. Rizzo JD, Lichtin AE, Woolf SH, et al. Use of epoetin in patients with cancer: evidence-based clinical practice guidelines of the American Society of Clinical Oncology and the American Society of Hematology. Blood 2002;100(7):2303-20.
11. Volberding P, Levine A, Dieterich D, et al. Anemia in HIV infection: clinical impact and evidence-based management strategies. Clin Infect Dis 2004;38:1454-63.
12. Yee HS, Currie SL, Darling JM, et al. Management and treatment of hepatitis c viral infection: recommendations from the Department of Veterans Affairs Hepatitis C Resource Center Program and the National Hepatitis C Program Office. Am J Gastroenterol 2006;101:2360-78.
13. AHRQ Evidence Report #29: Health Services/Technology Assessment Text. Use of erythropoietin for anemia in chronic renal failure. Available at: https://www.ncbi.nlm.nih.gov/books/NBK11934/. Accessed on November 3, 2020.
14. Remuzzi G, Ingelfinger JR. Correction of anemia-payoffs and problems. N Engl J Med. 2006;355:2144-6.
15. Drueke TB, Locatelli F, Clyne N,et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. N Engl J Med. 2006 Nov 16;355(20):2071-84.
16. Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 2006;355:2085-98.
17. Besarab A, Bolton WK, Browne JK, et al. The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin. N Engl J Med 1998;339:584-90.
18. Centers for Medicare and Medicaid Services. Decision memo for erythropoiesis stimulating agents (ESAs) for non-renal disease indications (CAG-00383N). July 30, 2007.
19. Rizzo J, Brouwers M, Hurley P, et al.American Society of Clinical Oncology/American Society of Hematology Clinical Practice Guideline Update on the Use of Epoetin and Darbepoetin in Adult Patients With Cancer Available at: http://jco.ascopubs.org/content/early/2010/10/25/JCO.2010.29.2201.full.pdf+html. Accessed February 21, 2011.
20. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed October 18, 2023.
21. Centers for Medicare and Medicaid Services. Medicare Program: End-Stage Renal Disease Prospective Payment System: Final Rule and Proposed Rule. Federal Register. 2010;75(155):49030-49214.
22. National Kidney Foundation. KDOQI clinical practice guidelines for chronic kidney disease: evaluation, classification and stratification. Am J Kidney Dis;39(Suppl 1):S1-266.
23. Groopman JE, Itri LM. Chemotherapy-induced anemia in adults: Incidence and treatment. J Natl Cancer Inst.1999;91(19):1616-34Available at: http://jnci.oxfordjournals.org/content/91/19/1616.full.pdf+html. Accessed March 18, 2011.
24. Grossman HA, Goon B, Bowers P, Leitz G. Once-weekly epoetin alfa dosing is as effective as three times-weekly dosing in increasing hemoglobin levels and is associated

with improved quality of life in anemic HIV-infected patients. J Acquir Immune Defic Syndr. 2003;34(4):368-78.
25. Revicki DA, Brown RE, Henry DA, et al. Recombinant human erythropoietin and health-related quality of life of AIDS patients with anemia. J Acquir Immune Defic Syndr. 1994;7:474-84.
26. Phair JP, Abels RI, McNeill MV, Sullivan DJ. Recombinant human erythropoietin treatment: investigational new drug protocol for the anemia of the acquired immunodeficiency syndrome. Arch Intern Med. 1993;153:2668-75.
27. Saag MS, Bowers P, Leitz GJ, Levine AM. Once-weekly epoetin alfa improves quality of life and increases hemoglobin in anemic HIV+ patients. AIDS Res Hum Retroviruses. 2004;20(10):1037-45.
28. HIV-associated cytopenias. UpToDate. Available at Uptodate.com. Accessed October 31, 2022.
29. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279-335. http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf. Accessed November 3, 2020.
30. The American Cancer Society website. Available at: https://www.cancer.org/cancer/glossary.html?letter=. Accessed November 3, 2020.
31. Mircera prescribing information. Vifor (International) Inc. St. Gallen, Switzerland. March 2023.
32. Centers for Medicare and Medicaid Services. Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule. Federal Register. 2014;79(215):66120-66265.
33. Retacrit prescribing information. Pfizer Inc. New York, NY. April 2023.
34. Per clinical consult with hematologist/oncologist, June 6, 2018.
35. EASL Clinical Practice Guidelines: Management of hepatitis C virus infection. J Hepatol. 2011;55(2):245-64.

5 . Revision History

Date	Notes
11/20/2023	2023 annual review: For anemia in myelodysplastic syndromes (MD S) indication, updated reauth criterion for positive response of hemog lobin level from increase of at least 1 g/dL from pre-treatment to incre ase of at least 1.5 g/dL to align with NCCN guidelines.

Evrysdi (risdiplam)

Prior Authorization Guideline

Guideline ID	GL-135210
Guideline Name	Evrysdi (risdiplam)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	10/21/2020
P&T Revision Date:	12/16/2020 ; 10/20/2021 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022 ; 10/18/2023

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 (HFMSE)
- 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 request ing risdiplam are not necessary in order to not delay access to initial t herapy in recently diagnosed infants. Initial assessments shortly post-t herapy 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]

4 . References

1. Evrysdi prescribing information. Genentech, Inc. South San Francisco, CA. October 2023.
2. Day JW, Annoussamy M, Baranello G, et al. SUNFISH Part 2: 24-month efficacy outcomes of risdiplam (RG7916) treatment in patients with Type 2 or 3 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.
3. Servais L, Baranello G, Masson R, et al. FIREFISH Part 2: Efficacy and safety of risdiplam (RG7916) in infants with Type 1 spinal muscular atrophy (SMA). Presented at the 2020 Virtual SMA Research & Clinical Care Meeting. June 12, 2020.
4. Markowitz JA, Sing P, Darras BT. Spinal muscular atrophy: a clinical and research update. Pediatr Neurol. 2012;46(1):1-12.
5. Wang CH, Finkel RS, Bertini ES, et al. Consensus statement for standard of care in spinal muscular atrophy. J Child Neurol. 2007;22(8):1027-1049.
6. Bertini E DJ, Muhaizea A, et al. RAINBOWFISH: A Study of Risdiplam (RG7916) in Newborns with Presymptomatic Spinal Muscular Atrophy. Presented at: World Muscle Society; October 1–5, 2019; Copenhagen, Denmark.
7. Mercuri E, Finkel RS, Muntoni F, et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. J Neuromuscul Dis. 2018;28(2):103-115.

8. Stolte B, Bois JM, Kizina K, et al. Minimal clinically important differences in functional motor scores in adults with spinal muscular atrophy. Eur. J. Neurol. 2020; 0:1-9.
9. Pera, M., Coratti, G., Mazzone, E., et al. (2019). Revised upper limb module for spinal muscular atrophy: 12 month changes. Muscle Nerve. Apr;59(4):426-430.
10. Kirschner J, Butoianu N, Goemans N, et al. European ad-hoc consensus statement on gene replacement therapy for spinal muscular atrophy. Eur J Paediatr Neurol. 2020. https://doi.org/10.1016/j.ejpn.2020.07.001
11. Evrysdi [AMCP dossier]; South San Francisco, CA: Genentech; September 2020.

5 . Revision History

Date	Notes
10/19/2023	Annual Review

Fabry Disease Agents

Prior Authorization Guideline

Guideline ID	GL-137687
Guideline Name	Fabry Disease Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/20/2004
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 05/20/2021 ; 10/20/2021 ; 10/19/2022 ; 07/19/2023 ; 08/17/2023 ; 11/16/2023 ; 11/16/2023

1 . Indications

Drug Name: Fabrazyme (agalsidase beta)
Fabry disease Indicated for the treatment of adult and pediatric patients 2 years of age and older with confirmed Fabry disease.
Drug Name: Elfabrio (pegunigalsidase alfa-iwxj)
Fabry disease Indicated for the treatment of adults with confirmed Fabry disease.

2 . Criteria

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

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Patient is 2 years of age or older

AND

3 - 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

4 - Will not be used in combination with other drugs used for Fabry disease [A]

Product Name: Fabrazyme	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Elfabrio

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

Approval Criteria

1 - Diagnosis of Fabry disease

AND

2 - Disease confirmed by 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 - Will not be used in combination with other drugs used for Fabry Disease [A]

Product Name: Elfabrio	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. The safety and effectiveness of concomitant use of Galafold (migalastat) and Fabrazyme (agalsidase beta) has not been established. [2, 6]

4 . References

1. Fabrazyme prescribing information. Genzyme Corporation. Cambridge, MA. August 2023.
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 Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.
5. Elfabrio prescribing information. Chiesi USA, Inc. Cary, NC. May 2023.
6. UptoDate. Fabry disease:Treatment and prognosis. Available at: https://www.uptodate.com/contents/fabry-disease-treatment-and-prognosis?search=fabry%20disease&source=search_result&selectedTitle=2~68&usage_type=default&display_rank=2. Accessed November 1, 2023.

5 . Revision History

Date	Notes
12/12/2023	Updated reauth verbiage

Galafold (migalastat)

Prior Authorization Guideline

Guideline ID	GL-135598
Guideline Name	Galafold (migalastat)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/14/2018
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 08/17/2023 ; 11/16/2023

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. June 2023.
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 Pratice. Am J Med Sci. 2020;360(6):641-649. doi:10.1016/j.amjms.2020.07.011.

5 . Revision History

Date	Notes
11/1/2023	Annual Review, no changes.

Gamifant (emapalumab-lzsg)

Prior Authorization Guideline

Guideline ID	GL-134062
Guideline Name	Gamifant (emapalumab-lzsg)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 02/16/2023 ; 2/16/2023

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 - Patient demonstrates 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.

5 . Revision History

Date	Notes
9/29/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Gattex (teduglutide)

Prior Authorization Guideline

Guideline ID	GL-118907
Guideline Name	Gattex (teduglutide)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	01/15/2020 ; 01/20/2021 ; 01/19/2022 ; 06/15/2022 ; 2/16/2023

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 - Documentation 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 - Documentation 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. Takeda Pharmaceuticals America, Inc. Lexington, MA. October 2022.
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.
9. DiBaise, J. UptoDate. Management of the short bowel syndrome in adults. November 2022. Available at: https://www.uptodate.com/contents/management-of-the-short-bowel-syndrome-in-

adults?search=GATTEX&source=search_result&selectedTitle=2~8&usage_type=default&display_rank=1. Accessed December 30, 2022.
10. Stamm, D., Duggan, C. UptoDate. Management of short bowel syndrome in children. November 2022. Available at: https://www.uptodate.com/contents/management-of-short-bowel-syndrome-in-children?search=GATTEX&source=search_result&selectedTitle=3~8&usage_type=default&display_rank=2. Accessed December 30, 2022.
11. Iyer, K., DiBaise, J., et al. AGA Clinical Practice Update on Management of Short Bowel Syndrome: Expert Review. June 2022. Available at: https://www.cghjournal.org/article/S1542-3565(22)00561-4/fulltext#pageBody. Accessed December 30, 2022.

5 . Revision History

Date	Notes
12/30/2022	2023 Annual Review

Prior Authorization Guideline

Guideline ID	GL-136641
Guideline Name	Gaucher Disease Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/20/2000
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 05/19/2022 ; 02/16/2023 ; 12/13/2023

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: Elelyso (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), Yargesa (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

Approval Criteria

1 - Diagnosis of Type 1 Gaucher disease

AND

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

AND

3 - Patient is 18 years of age or older

Product Name: Brand Zavesca, Yargesa or Generic miglustat	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of mild to moderate Type 1 Gaucher disease [E]

AND

2 - Patient is 18 years of age or older

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. Elelyso Prescribing Information. Pfizer, Inc. New York, NY. August 2022.
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. Titusville, NJ. August 2022.
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 January 5, 2023.
11. Per clinical consult with geneticist, November 11, 2010.
12. Yargesa Prescribing Information. Edenbridge Pharmaceuticals LLC. Parsippany, NJ. October 2023.

5 . Revision History

Date	Notes
11/23/2023	Added branded generic for Zavesca 100mg capsules.

Gazyva (obinutuzumab)

Prior Authorization Guideline

Guideline ID	GL-127461
Guideline Name	Gazyva (obinutuzumab)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/18/2014
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Gazyva (obinutuzumab)
Chronic Lymphocytic Leukemia (CLL) Indicated for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) in combination with chlorambucil. **Follicular Lymphoma (FL)** 1) Indicated in combination with bendamustine followed by Gazyva monotherapy for the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to, a rituximab-containing regimen. 2) Indicated for the treatment of adult patients with previously untreated stage II bulky, III or IV follicular lymphoma in combination with chemotherapy followed by Gazyva monotherapy in patients achieving at least a partial remission. **Off Label Uses: Small Lymphocytic Lymphoma (SLL) [2]**

2 . Criteria

Product Name: Gazyva	
Diagnosis	Chronic Lymphocytic Leukemia (CLL)/ Small Lymphocytic Leukemia (SLL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of chronic lymphocytic leukemia (CLL) and is previously untreated for CLL
- Diagnosis of small lymphocytic leukemia (SLL) and previously untreated for SLL [A]

AND

2 - Used in combination with chlorambucil [2,3]

Product Name: Gazyva	
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 - One of the following:

2.1 All of the following:

2.1.1 Relapsed or refractory to a rituximab-containing regimen [B]

AND

2.1.2 Will be used in combination with bendamustine for six cycles prior to maintenance treatment with Gazyva monotherapy

OR

2.2 All of the following:

2.2.1 Diagnosis of stage II bulky, III or IV follicular lymphoma

AND

2.2.2 Patient has not been treated with prior therapy

AND

2.2.3 Both of the following:

- Used in combination with chemotherapy until at least partial remission has been achieved
- Followed by Gazyva monotherapy

Product Name: Gazyva	
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. The National Comprehensive Cancer Network (NCCN) guidelines support the use of obinutuzumab for the treatment of small lymphocytic leukemia (SLL). One clinical trial showed the combination of obinutuzumab plus chlorambucil resulted in significant improvement in the median progression free survival (PFS) compared to chlorambucil alone (26.7 months vs 11.1 months, respectively). [2]
B. NCCN supports use of obinutuzumab in the treatment of follicular lymphoma as maintenance therapy for rituximab refractory disease in patients with indications for treatment as second-line extended dosing. [2]

4 . References

1. Gazyva Prescribing Information, Genentech Inc. San Francisco, CA. July 2022.
2. NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
3. National Comprehensive Cancer Network(NCCN) Practice Guidelines in Oncology. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma v3.2021. Available at: https://www.nccn.org/professionals/physician_gls/ pdf/cll.pdf. Accessed March 10, 2023.
4. Sharman JP, Banerji V, Fogliatto LM, et al. ELEVATE TN: Phase 3 study of acalabrutinib combined with obinutuzumab (O) or alone vs O plus chlorambucil (Clb) in patients (Pts) with treatment-naïve chronic lymphocytic leukemia (CLL). Blood. 2019;134 (Supplement_1):31.

5 . Revision History

Date	Notes
7/3/2023	Removed specialist requirement

Prior Authorization Guideline

Guideline ID	GL-135672
Guideline Name	Gilenya (fingolimod) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/14/2022
P&T Revision Date:	11/16/2023

1 . Indications

Drug Name: Gilenya (fingolimod)
Multiple Sclerosis 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: Generic fingolimod, Brand Gilenya 0.25mg	
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 - Patient is 10 years of age or older

AND

2 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
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 - Patient is 10 years of age or older

AND

2 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya, generic fingolimod	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

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

AND

2 - Failure after a trial of at least 4 weeks, or intolerance to generic fingolimod (applies to Brand Gilenya 0.5mg only)

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

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 - Patient is 10 years of age or older

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Gilenya 0.5mg	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

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

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, or intolerance to generic fingolimod

AND

3 - Not used in combination with another disease-modifying therapy for MS [E, 5, 6]

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. [3] The effectiveness of interferon beta in SPMS patients without relapses is uncertain. [2]
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. [2]
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. [2]

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. [4]
E. 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. [5, 6]

4 . References

1. Gilenya Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
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. National Multiple Sclerosis Society. Types of MS. Available at: https://www.nationalmssociety.org/What-is-MS/Types-of-MS. Accessed March 29, 2019.
4. Per clinical consultation with MS specialist, December 29, 2010.
5. Wingerchuk, D., & Carter, J. (2014). Multiple Sclerosis: Current and Emerging Disease-Modifying Therapies and Treatment Strategies. Mayo Clinic Proceedings, 89(2), 225-240.
6. 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.

5 . Revision History

Date	Notes

11/1/2023	2023 UM Annual Review. Updated initial auth to include age criteria. Updated standard reauth criteria to say "Patient demonstrates positive clinical response to therapy". Updated references.

Gilotrif (afatinib)

Prior Authorization Guideline

Guideline ID	GL-127295
Guideline Name	Gilotrif (afatinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/8/2013
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Gilotrif (afatinib)
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. **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.

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 a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).

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 (e.g., cisplatin, carboplatin)

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. April 2022.

4 . Revision History

Date	Notes
6/29/2023	Removed specialist requirement

Gleevec (imatinib mesylate) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-132181
Guideline Name	Gleevec (imatinib mesylate) - PA, NF

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	8/24/2001
P&T Revision Date:	12/18/2019 ; 09/15/2021 ; 03/16/2022 ; 09/21/2022 ; 05/18/2023 ; 07/19/2023 ; 9/20/2023

1 . Indications

Drug Name: Gleevec (imatinib mesylate)
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. **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. **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. **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.

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 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)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)

Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Chronic Myelogenous/Myeloid Leukemia (CML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome/BCR ABL-positive (Ph+/BCR ABL+) chronic myelogenous/myeloid leukemia (CML)

Product Name: Brand Gleevec	
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 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Acute lymphoblastic leukemia/ Acute lymphoblastic lymphoma (ALL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

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)

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib	
Diagnosis	Myelodysplastic Disease (MDS)/Myeloproliferative Disease (MPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of myelodysplastic/myeloproliferative disease (MDS/MPD)

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

Product Name: Generic imatinib

Diagnosis	Aggressive Systemic Mastocytosis (ASM)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of aggressive systemic mastocytosis (ASM)

Product Name: Brand Gleevec	
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 - Trial and failure, or intolerance to generic imatinib

Product Name: Brand Gleevec	
Diagnosis	Hypereosinophilic Syndrome (HES) and/or Chronic Eosinophilic Leukemia (CEL)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of at least one of the following:

- Hypereosinophilic syndrome (HES)
- Chronic eosinophilic leukemia (CEL)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

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)

Product Name: Brand Gleevec	
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)

AND

2 - Trial and failure, or intolerance to generic imatinib

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

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)

Product Name: Brand Gleevec	
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 - Trial and failure, or intolerance to generic imatinib

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 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, or intolerance to generic imatinib

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)

Product Name: Brand Gleevec, Generic imatinib	
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. Gleevec Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2021.

4 . Revision History

Date	Notes
8/31/2023	Annual Review - no criteria changes

Gonadotropin-Releasing Hormone Agonists

Prior Authorization Guideline

Guideline ID	GL-128175
Guideline Name	Gonadotropin-Releasing Hormone Agonists

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	12/12/2005
P&T Revision Date:	12/18/2019 ; 02/13/2020 ; 07/15/2020 ; 09/16/2020 ; 01/20/2021 ; 09/15/2021 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 01/18/2023 ; 06/21/2023 ; 8/17/2023

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 1-Month 3.75 mg, 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. Use of norethindrone acetate in combination with LUPRON DEPOT is referred to as add-back therapy, and is intended to reduce the loss of bone mineral density (BMD) and reduce vasomotor symptoms associated with use of LUPRON DEPOT. Limitations of Use: The total duration of therapy with LUPRON DEPOT 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. Consider a one-month trial period on iron alone, as some women will respond to iron alone. LUPRON DEPOT may be added if the response to iron alone is considered inadequate. 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. [17]

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, Eligard (leuprolide acetate), Trelstar (triptorelin pamoate)

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: Camcevi (leuprolide)

Prostate Cancer Indicated for the treatment of adult patients with advanced prostate cancer.

Drug Name: Fensolvi (leuprolide acetate)

Central Precocious Puberty (CPP) Indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

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: 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

Approval Criteria

1 - Diagnosis of endometriosis

AND

2 - One of the following: [8, 12]

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:

- Danazol
- Combination (estrogen/progestin) oral contraceptive

- Progestins

OR

2.2 Patient has had surgical ablation to prevent recurrence

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

Approval Criteria

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]
Approval Length	4 month(s)
Guideline Type	Prior Authorization

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]
Approval Length	3 month(s)
Guideline Type	Prior Authorization

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: Camcevi, 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

Product Name: Eligard, Brand Leuprolide Acetate (22.5 mg), 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

AND

2 - Trial and failure, contraindication, or intolerance to any brand Lupron formulation

Product Name: Camcevi, Eligard, Brand Leuprolide Acetate (22.5 mg), 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

Approval Criteria

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

Product Name: Fensolvi, 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:

- 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: Fensolvi, Lupron Depot-PED, Supprelin LA, Triptodur	
Diagnosis	Central Precocious Puberty (CPP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

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) [22]

AND

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) [22]

AND

3 - Prescribed by or in consultation with a pediatric endocrinologist

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

Approval Criteria

1 - Diagnosis of infertility

AND

2 - Used as part of an assisted reproductive technology (ART) protocol

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Lupron Depot, Lupron Depot-PED, Brand Leuprolide Acetate (22.5 mg), Generic leuprolide acetate, Eligard, Supprelin LA, Trelstar, Triptodur, Camcevi, Fensolvi	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [16, 17]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Using gonadotropin for suppression of puberty [16,17]

AND

2 - Diagnosis of gender dysphoria/gender incongruence

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. January 2023.
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 July 13, 2023.
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. Ewing, NJ. March 2023.
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.

16. Hembree, Wylie C, Cohen-Kettenis P, Delemarre-van de Waal HA, et al. "Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline." The Journal of clinical endocrinology and metabolism 94.9 (2009):3132-3154.
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. Azurity Pharmaceuticals, Inc. Woburn, MA. December 2022.
19. Fensolvi prescribing information. Tolmar Inc. Fort Collins, CO. February 2023.
20. Camcevi Prescriber Information. Accord BioPharma, Inc. Durham, NC. November 2022.
21. Leuprolide Acetate Depot prescribing information. Cipla USA, Inc. Warren, NJ. March 2023.
22. 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.

5 . Revision History

Date	Notes
8/21/2023	Updated reauth criteria for central precocious puberty indication. Add ed Camcevi and Fensolvi to gender dysphoria/gender incongruence i ndication. Removed criteria for obsolete Lupaneta and Vantas produ cts.

Growth Hormones - PA, NF

Prior Authorization Guideline

Guideline ID	GL-136605
Guideline Name	Growth Hormones - PA, NF

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	08/15/2019 ; 05/14/2020 ; 08/13/2020 ; 08/19/2021 ; 12/15/2021 ; 06/15/2022 ; 08/18/2022 ; 01/18/2023 ; 07/19/2023 ; 08/17/2023 ; 09/20/2023 ; 11/16/2023 ; 11/16/2023

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

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- 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.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

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 T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. NOTE: Documentation of previous height, current height and goal expected adult height will be required for renewal. *Approve at N DC 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 T ransition Phase Adolescent or Adult who had childhood onset GH defi

	ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. *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

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- 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.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

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

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 T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency. NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

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

Approval Criteria

1 - One of the following:

1.1 One of the following: [12]

1.1.1 Both of the following: [24-26]

- 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.)

OR

1.1.2 History of neonatal hypoglycemia associated with pituitary disease

OR

1.1.3 Diagnosis of panhypopituitarism

OR

1.2 Submission of medical records (e.g., chart notes) documenting 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 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 T ransition Phase Adolescent or Adult who had childhood onset GH defi ciency, utilize criteria for Transition Phase Adolescent or Adult GH Def iciency.

Product Name: Genotropin, Humatrope, Saizen, Zomacton	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
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, 23]

- 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: Skytrofa	
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 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

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

Product Name: Sogroya	
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 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)

AND

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

- Skytrofa
- Ngenla

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

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)

AND

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

- Skytrofa
- Ngenla

Product Name: Sogroya	
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 Submission of medical records (e.g., chart notes) documenting 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 2.5 years of age or older

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)

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:

- Skytrofa
- Ngenla

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal.

Product Name: Sogroya	
Diagnosis	Pediatric Growth Hormone Deficiency (GHD)
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, 23]

- 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)

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:

- Skytrofa
- Ngenla

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

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

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

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

Approval Criteria

1 - Diagnosis of Prader-Willi Syndrome [10, 11]

AND

2 - Prescribed by or in consultation with an endocrinologist

Notes	*Approve at NDC list "SOMATROPPA".

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

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

Notes	*Approve at NDC list "SOMATROPPA".

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):

- 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

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. *Approve at NDC list " SOMATROPPA".

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

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 "SOMATROPPA”.

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]

- Norditropin (somatropin)
- Nutropin (somatropin)
- Omnitrope (somatropin)

Notes	NOTE: Documentation of previous height, current height and goal exp ected 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

Approval Criteria

1 - Height increase of at least 2 cm/year over the previous year of treatment as documented by both of the following: [28]

- 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 [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

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 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):

- Birth weight
- Birth length

AND

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]

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 [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

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: [28]

- 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*, Nutropin AQ NuSpin* [off-label] [B, 11], Omnitrope*	
Diagnosis	Turner Syndrome or Noonan Syndrome
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

Notes	NOTE: Documentation of previous height, current height and goal exp ected adult height will be required for renewal. *Approve at NDC list " SOMATROPPA".

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

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 "SOMATROPPA".

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 exp ected adult height will be required for renewal.

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	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, 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

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 Submission of medical records (e.g., chart notes) documenting 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 Submission of medical records (e.g., chart notes) documenting 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 - 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 exp ected adult height will be required for renewal.*Approve at NDC list "S OMATROPPA".

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 "SOMATROPPA".

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

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

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 "SOMATROPPA".

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 "SOMATROPPA".

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 exp ected 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]
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

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

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

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 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: Norditropin Flexpro*, Nutropin AQ NuSpin*, Omnitrope*	
Diagnosis	Adult Growth Hormone Deficiency
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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
- Adrenocorticotropic 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 disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase. *Approve at NDC list "SOMATROPPA".

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

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

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.*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

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, 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 disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

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

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)

Notes	Use the following criteria for child- and adult-onset with pituitary disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

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	Non Formulary

Approval Criteria

1 - Diagnosis of adult GH deficiency as a result of one of the following: [10, 12, 21]

1.1 Submission of medical records (e.g., chart notes) supporting a diagnosis of childhood-onset GHD

OR

1.2 Both of the following:

1.2.1 Adult-onset GHD

AND

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)

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 disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

Product Name: Genotropin, Humatrope, Saizen, Sogroya, 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 disea se; use Isolated GHD in Adult criteria for patients without pituitary dise ase.

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 "SOMATROPPA".

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 "SOMATROPPA”.

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]
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

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	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
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 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, Sogroya, Zomacton	
Diagnosis	Transition Phase Adolescent Patients [off-label] [B]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

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 - 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*, Omnitrope*	
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

Notes	*Approve at NDC list "SOMATROPPA".

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

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

Notes	*Approve at NDC list "SOMATROPPA".

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, Sogroya, 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, Sogroya, Zomacton [off-label] [B, 21]	
Diagnosis	Isolated Growth Hormone Deficiency in Adults
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)

Product Name: Serostim	
Diagnosis	Human Immunodeficiency Virus (HIV)-Associated Cachexia
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HIV-associated wasting syndrome or cachexia [7, 15, 18, 19]

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/m^2

OR

2.5 All of the following

- Patient is male
- BCM less than 35% of total body weight
- BMI less than 27 kg/m^2

OR

2.6 All of the following

- Patient is female
- BCM less than 23% of total body weight
- BMI less than 27 kg/m^2

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]

- Weight
- BCM
- BMI

Product Name: Zorbtive	
Diagnosis	Short Bowel Syndrome
Approval Length	4 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Short Bowel Syndrome [9, 16]

AND

2 - Patient is currently receiving specialized nutritional support (e.g., intravenous parenteral nutrition, fluid, and micronutrient supplements) [9, 16]

AND **3** - Patient has not previously received 4 weeks of treatment with Zorbtive [9, 16]	
Notes	NOTE: Treatment with Zorbtive will not be authorized beyond 4 weeks . Administration for more than 4 weeks has not been adequately studi ed.

Product Name: All Products	
Guideline Type	Prior Authorization, Non Formulary
Approval Criteria **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]	
Notes	Approval Length: N/A - Requests for non-approvable diagnoses shoul d 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 ≤ - 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

1. Genotropin Prescribing Information. Pharmacia & Upjohn Co, a Division of Pfizer Inc. New York, NY. April 2019.
2. Humatrope Prescribing Information. Eli Lilly and Company. Indianapolis, IN. October 2019.
3. Norditropin Flexpro Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. March 2020.
4. Nutropin AQ NuSpin Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2016.
5. Omnitrope Prescribing Information. Sandoz Inc. Princeton, NJ. June 2019.
6. Saizen Prescribing Information. EMD Serono, Inc. Rockland, MA. February 2020.
7. Serostim Prescribing Information. EMD Serono, Inc. Rockland, MA. June 2019.
8. Zomacton Prescribing Information. Ferring Pharmaceuticals Inc. Parsippany, NJ. July 2018.
9. Zorbtive Prescribing Information. EMD Serono, Inc. Rockland, MA. September 2019.
10. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for GH use in adults and children-2003 update. Endocr Pract. 2003;9(1):64-76.
11. Wilson TA, Rose SA, Cohen P, et al. Update on guidelines for the use of GH in children: The Lawson Wilkins pediatric endocrinology society drug and therapeutics committee. J Pediatrics 2003 (Oct): 415-21
12. GH Research society. Consensus guidelines for the diagnosis and treatment of GH deficiency in childhood and adolescence: Summary statement. J Clin Endocinol Metab. 2000; 85: 3990-93.
13. Badaru A, Wilson DM. Alternatives to growth hormone stimulation testing in children. Trends Endocrinol Metab 2004;15(6):252-8.
14. Gandrud LM, Wilson DM. Is growth hormone stimulation testing in children still appropriate? Growth Horm IGF Res 2004;14(3):185-94.
15. Corcoran C, Grinspoon S. Treatment for wasting in patients with the acquired immunodeficiency syndrome. N Engl J Med 1999; 340 (22):1740-50.

16. Byrne TA, Wilmore DW, Iyer K et al. Growth hormone, glutamine, and an optimal diet reduces parenteral nutrition in patients with short bowel syndrome. Ann Surg 2005;242:655-61.
17. Polsky B, Kotler D, Steinhart C. HIV-associated wasting in the HAART era: guidelines for assessment, diagnosis, and treatment. AIDS Patient Care STDS. 2001;15:411-23.
18. Polsky B, Kotler D, Steinhart C. Treatment guidelines for HIV-associated wasting. HIV Clin Trials. 2004;5:50-61.
19. Nemechek P, Polsky B, Gottlieb M. Treatment guidelines for HIV-associated wasting. Mayo Clin Proc. 2000;75:386-394.
20. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. Endocr Pract. 2019;25(No. 11):1191-1232. Available at: https://www.sciencedirect.com/science/article/pii/S1530891X20351454. Accessed July 12, 2021.
21. Cook DM, Yuen KC, Biller BM, Kemp SF, Vance ML. American Association of Clinical Endocrinologists medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients -2009 update. Endocr Pract. 2009;15(suppl 2):1-29. Available at: https://www.researchgate.net/publication/38037397. Accessed July 12, 2021.
22. 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.
23. 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 June 21, 2019.
24. Wit JM, van Unen H. Growth of infants with neonatal growth hormone deficiency. Arch Dis Child. 1992; 67: 920-924.
25. Herber SM, Milner RD. Growth hormone deficiency presenting under age 2 years. Arch Dis Child. 1984 Jun; 59(6): 557–560.
26. Per clinical consult with pediatric endocrinologist, July 23, 2018.
27. Skytrofa Prescribing Information. Ascendis Pharma Endocrinology, Inc. Princeton, NJ. October 2022.
28. Sogroya Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. April 2023.
29. UpToDate. Diagnosis of growth hormone deficiency in children, Available at: https://www.uptodate.com/contents/diagnosis-of-growth-hormone-deficiency-in-children?search=pediatric%20gorwth%20hormone%20deficinecy&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#. Accessed June 22, 2023.
30. Thomas, H., and Kumar, B. The usefulness of serum IGF-1 and serum IGFBP-3 for the diagnosis of growth hormone deficiency in comparison to clonidine stimulation test: a prospective cohort study. Available at: file:///C:/Users/kdekhtaw/Downloads/medip,+IJCP-3963+O.pdf. Accessed June 22, 2023.
31. Ngenla Prescribing Information. Pfizer Laboratories Division of Pfizer Inc. New York, NY. June 2023.

5 . Revision History

Date	Notes
11/20/2023	Updated Sogroya Non-Formulary criteria.

Halaven (eribulin mesylate)

Prior Authorization Guideline

Guideline ID	GL-127107
Guideline Name	Halaven (eribulin mesylate)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/5/2011
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Halaven (eribulin mesylate)
Metastatic Breast Cancer Indicated for the treatment of patients with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting. **Liposarcoma** Indicated for the treatment of patients with unresectable or metastatic liposarcoma who have received a prior anthracycline-containing regimen.

2 . Criteria

Product Name: Halaven	
Diagnosis	Breast cancer

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: [1-2]

- Recurrent
- Metastatic

AND

3 - Previous treatment with both of the following:

- One anthracycline [e.g., doxorubicin, Ellence (epirubicin)]
- One taxane [e.g., paclitaxel, Taxotere (docetaxel)]

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

Approval Criteria

1 - Diagnosis of liposarcoma

AND

2 - Disease is one of the following:

- Unresectable
- Metastatic

AND

3 - Previous treatment with one anthracycline-containing regimen (e.g., doxorubicin, epirubicin)

Product Name: Halaven	
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. Halaven Prescribing Information. Eisai Inc.,Woodcliff Lake, NJ. September 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed Februrary 27, 2023.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Harvoni (ledipasvir/sofosbuvir) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-126039
Guideline Name	Harvoni (ledipasvir/sofosbuvir) - PA, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	10/14/2014
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 08/13/2020 ; 01/20/2021 ; 06/16/2021 ; 01/19/2022 ; 06/15/2022 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Harvoni (ledipasvir/sofosbuvir)
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, 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.

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

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 - 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

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 - Patient is treatment-naive

AND

4 - Submission of medical records documenting 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:

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)
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

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.

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

Approval Criteria

1 - 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 (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.

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

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 - 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 - 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. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 14, 2023.

4 . Revision History

Date	Notes
6/6/2023	Annual review - no criteria changes; background updates

Hereditary Angioedema Agents

Prior Authorization Guideline

Guideline ID	GL-135773
Guideline Name	Hereditary Angioedema Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/17/2009
P&T Revision Date:	06/21/2023 ; 11/16/2023

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: Sajazir (icatibant)

Acute treatment of Hereditary Angioedema (HAE) Indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

2 . Criteria

Product Name: Cinryze	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 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

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

AND

3 - For prophylaxis against HAE attacks [3]

AND

4 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

AND

5 - Patient is 6 years of age or older

AND

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

- Immunologist
- Allergist

Product Name: Cinryze	
Diagnosis	Prophylaxis of HAE attacks
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in the number or rate of HAE attacks while on therapy)

AND

2 - Not used in combination with other approved treatments for prophylaxis against HAE attacks

Product Name: Cinryze [off-label], Sajazir	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [A]

AND

2 - One of the following [A]:

2.1 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

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

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 Sajazir only)

AND

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

- Immunologist
- Allergist

Product Name: Cinryze [off-label], Sajazir	
Diagnosis	Treatment of acute HAE attacks
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 used in combination with other approved treatments for acute HAE attacks

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hereditary angioedema (HAE) [3, A]

AND

2 - One of the following [A]:

2.1 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

OR

2.2 Diagnosis has been confirmed by both of the following:

2.2.1 Patient has normal C1-INH levels (HAE-n1-C1INH previously referred to as HAE Type 3)

AND

2.2.2 One of the following:

- Confirmed presence of a FXII, plasminogen gene mutation, angiopoietin-1 mutation, or kininogen mutation
- Patient has recurrent angioedema attacks that are refractory to high-dose antihistamines (e.g., cetirizine) with a confirmed family history of recurrent angioedema

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 - Prescribed by or in consultation with one of the following: [B]

- Immunologist
- Allergist

Product Name: Berinert	
Diagnosis	Treatment of acute HAE attacks
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 used in combination with other approved treatments for acute HAE attacks

3 . Endnotes

A. HAE is a rare genetic disorder that can be broadly divided into two fundamental types: 1) HAE-C1INH (HAE Type 1 or Type 2), which presents with a deficiency of C1-INH; 2) HAE-n1-C1INH (previously referred to as HAE Type 3), a rare variant which presents with normal C1-INH levels. This condition is inherited in an autosomal dominant manner 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 Type 1 or Type 2 HAE requires laboratory testing to confirm low or abnormal levels of C1-inhibitor. HAE-n1-C1INH (previously referred to as HAE Type 3) presents a diagnostic challenge given the current lack of a validated biochemical test to confirm diagnosis. Per HAE guidelines, when a diagnosis of HAE-n1-CINH is suspected based on normal C1-INH levels, diagnosis should be confirmed by a known mutation associated with the disease or a positive family history of recurrent angioedema with a lack of efficacy to high-dose antihistamine therapy [10, 14].

B. Includes immunologist and allergist 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]

4 . References

1. Cinryze Prescribing Information. Shire ViroPharma, Inc. Lexington, MA. February 2023.
2. Micromedex Healthcare Series [internet database]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc. Updated periodically. Available at: http://www.thomsonhc.com/. Accessed July 30, 2019.
3. Berinert Prescribing Information. CSL Behring, LLC. Kankakee, IL. September 2021.
4. FDA/CDER. Briefing Document for Blood products Advisory Committee. Presented May 2, 2008. Available at: http://www.fda.gov/. Accessed July 30, 2019.
5. Craig TJ, Levy RJ, Wasserman RL. Efficacy of human C1 esterase inhibitor concentrate compared with placebo in acute hereditary angioedema attacks. J Allergy Clin Immunol. Oct 2009;124(4):801-8.
6. Cicardi M, Zura B. Hereditary angioedema: Pathogenesis and diagnosis. UpToDate Web site. Available at: http://www.uptodate.com/. Accessed July 30, 2019.
7. Sajazir Prescribing Information. Cipla Ltd., India. May 2022.
8. Busse PJ, Christiansen SC, et. al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract 2020.

5 . Revision History

Date	Notes
11/1/2023	Updated initial criteria. Added reauthorization criteria. Updated backg round.

Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-134201
Guideline Name	Hetlioz, Hetlioz LQ (tasimelteon) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/8/2014
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 02/18/2021 ; 06/16/2021 ; 08/19/2021 ; 07/20/2022 ; 02/16/2023 ; 07/19/2023 ; 7/19/2023

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

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 hypernychthemeral 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: 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

Approval Criteria

1 - Patient demonstrates 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

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

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 - Patient demonstrates 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)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 hypernychthemeral 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)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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)
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.

5 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes t o clinical intent

Human Chorionic Gonadotropin (hCG)

Prior Authorization Guideline

Guideline ID	GL-135822
Guideline Name	Human Chorionic Gonadotropin (hCG)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/20/2001
P&T Revision Date:	07/15/2020 ; 11/12/2020 ; 09/15/2021 ; 10/19/2022 ; 09/20/2023 ; 09/20/2023 ; 9/20/2023

1 . Indications

Drug Name: Novarel (chorionic gonadotropin), Pregnyl (chorionic gonadotropin)
Ovulation Induction (OI) Indicated for the induction of ovulation (OI) and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins. **Prepubertal Cryptorchidism** Indicated for prepubertal cryptorchidism not due to anatomic obstruction. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases the response is temporary. Therapy is usually instituted between the ages of 4 and 9. **Hypogonadotropic Hypogonadism** Indicated for the treatment of selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males. **Off Label Uses: Infertile women undergoing Assisted Reproductive Technologies (ART)** Used for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated

with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer. [3]
Drug Name: Ovidrel (chorionic gonadotropin) PreFilled Syringe
Infertile women undergoing Assisted Reproductive Technologies (ART) Indicated for the induction of final follicular maturation and early luteinization in infertile women who have undergone pituitary desensitization and who have been appropriately pretreated with follicle-stimulating hormones (FSH) as part of an assisted reproductive technology (ART) program such as in vitro fertilization and embryo transfer. **Ovulation Induction (OI)** Indicated for the induction of ovulation (OI) and pregnancy in anovulatory infertile patients in whom the cause of infertility is functional and not due to primary ovarian failure.

2 . Criteria

Product Name: Pregnyl*	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Pregnyl*	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND

2 - For the development of multiple follicles (controlled ovarian hyperstimulation)

AND

3 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Pregnyl	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name: Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name: Pregnyl	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

Product Name: Generic chorionic gonadotropin*, Novarel*, Ovidrel*	
Diagnosis	Ovulation Induction [4, 6]
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of anovulatory infertility

AND

2 - Infertility is not due to primary ovarian failure

AND

3 - For induction of ovulation

AND

4 - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Generic chorionic gonadotropin*, Novarel*, Ovidrel*	
Diagnosis	Controlled Ovarian Hyperstimulation
Approval Length	2 Months (or per plan benefit design)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infertility

AND **2** - For the development of multiple follicles (controlled ovarian hyperstimulation) **AND** **3** - Patient has been pre-treated with a follicular stimulating agent (e.g., gonadotropins, clomiphene citrate, letrozole)

Notes	*Please consult client-specific resources to confirm whether benefit ex clusions should be reviewed for medical necessity.

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Prepubertal Cryptorchidism
Approval Length	6 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction [A]

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of male hypogonadism secondary to pituitary deficiency

AND

2 - Low testosterone (below normal reference level provided by the physician's laboratory)

AND

3 - One of the following:

- Low LH (below normal reference level provided by the physician's laboratory)
- Low FSH (below normal reference level provided by the physician's laboratory)

Product Name: Generic chorionic gonadotropin, Novarel, Ovidrel	
Diagnosis	Male Hypogonadotropic Hypogonadism [4, 5]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy.

3 . Endnotes

A. In general, hCG is thought to induce testicular descent in situations when descent would have occurred at puberty. hCG thus may help predict whether or not orchiopexy (operation to bring an undescended testicle into the scrotum) will be needed in the future. Although, in some cases, descent following hCG administration is permanent, in most cases, the response is temporary. Therapy is usually initiated between the ages of 4 and 9. [1, 2, 4]

4 . References

1. Novarel prescribing information. Ferring Pharmaceuticals Inc. Parsippany, NJ. June 2023.
2. Pregnyl prescribing information. Merck & Co., Inc. Whitehouse Station, NJ. March 2023.
3. Ovidrel prescribing information. EMD Serono, Inc. Rockland, MA. February 2022.
4. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed August 9, 2021.
5. Petak SM, Nankin HR, Spark RF, Swerdloff RS, Rodriguez-Rigau LJ. American Association of Clinical Endocrinologists Medical Guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients – 2002 update. Endocr Pract. 2002;8:440-456.
6. The Practice Committee of the American Society for Reproductive Medicine. Use of exogenous gonadotropins in anovulatory women: a technical bulletin. Fertil Steril. 2008;90:S7-12.

5 . Revision History

Date	Notes
11/2/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Hydroxyprogesterone caproate injection products

Prior Authorization Guideline

Guideline ID	GL-133886
Guideline Name	Hydroxyprogesterone caproate injection products

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	5/17/2011
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 12/14/2022 ; 10/18/2023

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

Approval Criteria

1 - Patient had a previous singleton (single offspring) spontaneous preterm birth

AND

2 - Patient is having a singleton pregnancy

AND

3 - Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation

AND

4 - Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first

AND

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

- 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 it s generic.

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

Approval Criteria

1 - Used for production of secretory endometrium and desquamation

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s 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

Approval Criteria

1 - Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus

AND

2 - Patient is not pregnant

AND

3 - Prescribed by or in consultation with an oncologist

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s 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

Approval Criteria

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

AND

2 - Patient is not pregnant

Notes	Note: This product and its criteria do NOT apply to brand Makena or it s 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

Approval Criteria

1 - Used for the testing of endogenous estrogen production

AND

2 - Patient is not pregnant	
Notes	Note: This product and its criteria do NOT apply to brand Makena or it s 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. December 2022.
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.

6 . Revision History

Date	Notes
9/27/2023	2023 UM Annual Review. No criteria changes. Updated references.

HyQvia (immune globulin with recombinant human hyaluronidase)

Prior Authorization Guideline

Guideline ID	GL-124896
Guideline Name	HyQvia (immune globulin with recombinant human hyaluronidase)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 5/18/2023

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.

4 . Revision History

Date	Notes
5/3/2023	Addition of age criterion

Ibrance (palbociclib)

Prior Authorization Guideline

Guideline ID	GL-129186
Guideline Name	Ibrance (palbociclib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/14/2015
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 03/15/2023 ; 05/18/2023 ; 06/21/2023 ; 07/19/2023 ; 8/17/2023

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 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kisqali (ribociclib)
- Verzenio (abemaciclib)

OR

2.2 For continuation of prior therapy

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.

4 . Revision History

Date	Notes
8/3/2023	Addition of a step through Kisqali and Verzenio

Iclusig (ponatinib)

Prior Authorization Guideline

Guideline ID	GL-136518
Guideline Name	Iclusig (ponatinib)

Guideline Note:

Effective Date:	2/1/2024
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/12/2020 ; 02/18/2021 ; 11/18/2021 ; 11/17/2022 ; 05/18/2023 ; 07/19/2023 ; 12/13/2023

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. Limitations of Use: Iclusig is not indicated and is not recommended for the treatment of patients with newly diagnosed CP-CML **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

Approval Criteria

1 - Diagnosis of chronic myelogenous leukemia (CML)

Product Name: Iclusig	
Diagnosis	Chronic Myelogenous 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

Product Name: Iclusig	
Diagnosis	Acute Lymphoblastic Leukemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia

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 . Endnotes

A. Resistance in CP-CML while on prior TKI therapy, was defined as failure to achieve either a complete hematologic response (by 3 months), a minor cytogenetic response (by 6 months), or a major cytogenetic response (by 12 months). Patients with CP-CML who experienced a loss of response or development of a kinase domain mutation in the absence of a complete cytogenetic response or progression to AP-CML or BP-CML at any time on prior TKI therapy were also considered resistant. Resistance in AP-CML, BP-CML, and Ph+ALL was defined as failure to achieve either a major hematologic response (by 3 months in AP-CML, and by 1 month in BP-CML and Ph+ALL), loss of major hematologic response (at any time), or development of a kinase domain mutation in the absence of a complete major hematologic response while on prior TKI therapy. Intolerance was defined as the discontinuation of prior TKI therapy due to toxicities despite optimal management in the absence of a complete cytogenetic response in patients with CP-CML or major hematologic response for patients with APCML, BP-CML, or Ph+ALL. [1]

4 . References

1. Iclusig Prescribing Information. ARIAD Pharmaceuticals, Inc. Cambridge, MA. February 2022.

5 . Revision History

Date	Notes

12/1/2023	Annual review - updated indications to include limitations to use; upd ated references.

Ilaris (canakinumab injection)

Prior Authorization Guideline

Guideline ID	GL-135970
Guideline Name	Ilaris (canakinumab injection)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/17/2009
P&T Revision Date:	08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 10/19/2022 ; 08/17/2023 ; 08/17/2023 ; 10/18/2023

1 . Indications

Drug Name: Ilaris (canakinumab injection)
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. **Systemic Juvenile Idiopathic Arthritis (SJIA)** Indicated for the treatment of active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and older. **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.

Gout Flares Indicated for the symptomatic treatment of adult patients with gout flares in whom nonsteroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate.

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

Approval Criteria

1 - Diagnosis of one of the following periodic fever syndromes:

- 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)

AND

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

- Immunologist
- Allergist
- Dermatologist
- Rheumatologist
- Neurologist

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])

Product Name: Ilaris	
Diagnosis	Periodic Fever Syndrome [CAPS, TRAPS, HIDS/MKD, FMF]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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	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 (SJIA)

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 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2]:

- 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

Approval Criteria

1 - Diagnosis of Still’s Disease, including Adult-Onset Still’s Disease (AOSD)

AND

2 - Trial and failure, contraindication, or intolerance to one of the following: [1-3]

- Corticosteroids (e.g., prednisone)
- Methotrexate
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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	Gout Flares
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gout flares

AND

2 - Trial and failure, contraindication, or intolerance to ALL of the following [1, 6]:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen)
- Colchicine
- Corticosteroids (e.g., prednisone)

AND

3 - Patient has not received Ilaris in the last 12 weeks [A]

AND

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

- Rheumatologist
- Nephrologist

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 . Endnotes

A. The recommended dose of Ilaris for adult patients with a gout flare is 150 mg administered subcutaneously. In patients who require re-treatment, there should be an interval of at least 12 weeks before a new dose of Ilaris may be administered [1].

5 . References

1. Ilaris Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2023.
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.
6. FitzGerald JD, Dalbeth N, Mikuls T, et al. 2020 American College of Rheumatology guideline for the management of gout. Arthritis Care Res. 2020;72(6):744-760.

6 . Revision History

Date	Notes
11/5/2023	12/1/23: Addition of criteria for the new gout flares indication. 1/1/24: Program update to standard reauthorization language. No ch anges to clinical intent.

Imbruvica (ibrutinib)

Prior Authorization Guideline

Guideline ID	GL-135759
Guideline Name	Imbruvica (ibrutinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/18/2014
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 05/18/2023 ; 07/19/2023 ; 08/17/2023

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

Approval Criteria

1 - Diagnosis of one of the following:

- 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

Approval Criteria

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

Product Name: Imbruvica	
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

Product Name: Imbruvica	
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

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

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)

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

Approval Criteria

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

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

Approval Criteria

1 - Diagnosis of one of the following:

- chronic lymphocytic leukemia
- small lymphocytic lymphoma

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	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

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 graft versus host disease (cGVHD)
Approval Length	12 month(s)
Guideline Type	Non Formulary

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** - 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.

4 . Revision History

Date	Notes
11/2/2023	Drug Specific NF criteria applied.

Prior Authorization Guideline

Guideline ID	GL-135489
Guideline Name	Immune Globulins - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/5/2000
P&T Revision Date:	07/17/2019 ; 09/18/2019 ; 08/15/2019 ; 10/16/2019 ; 11/14/2019 ; 12/18/2019 ; 04/15/2020 ; 05/14/2020 ; 04/21/2021 ; 09/15/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 04/20/2022 ; 04/19/2023 ; 4/19/2023

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
Approval Length	12 month(s)
Guideline Type	Prior Authorization

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 x 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 x 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

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

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: Asceniv, Panzyga	
Diagnosis	Kawasaki Disease (KD) [5, 7-9]
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Kawasaki Disease [5]

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]
Approval Length	12 month(s)
Guideline Type	Prior Authorization

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]
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

Approval Criteria

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 - 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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as measured by an objective scale (e.g., Rankin, Modified Rankin, Medical Research Council [MRC] scale) [77, H, P]

AND

2 - Documentation of titration to the minimum dose and frequency needed to maintain a sustained clinical effect [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

Approval Criteria

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

Approval Criteria

1 - For prophylaxis of Hepatitis A before or soon after exposure [57, 93]

AND

2 - Patient does not have clinical manifestations of hepatitis A [57, 93]

AND

3 - Patient does not have exposure to hepatitis A for more than 2 weeks previously [57, 93]

Product Name: Gamastan	
Diagnosis	Measles (Rubeola)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For use in susceptible individuals exposed to measles fewer than 6 days previously [57, 93]

AND

2 - Patient is not receiving measles vaccine at the same time [57, 93]

Product Name: Gamastan

Diagnosis	Varicella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization against varicella [57, 93]

AND

2 - Patient is immunosuppressed [57, 93]

AND

3 - Varicella Zoster Immune Globulin (Human) vaccine is not available

Product Name: Gamastan	
Diagnosis	Rubella
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - For pregnant women who are exposed or susceptible to Rubella [57, 93]

AND

2 - Patient will not consider a therapeutic abortion [57, 93]

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

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 - 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]
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

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 - Patient demonstrates 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

Approval Criteria

1 - Diagnosis of multifocal motor neuropathy (MMN) as confirmed by all of the following [76, 86, 87, N]:

1.1 Weakness with slowly progressive or stepwise progressive course over at least one month

AND

1.2 Asymmetric involvement of two or more nerves

AND

1.3 Absence of both of the following:

1.3.1 Motor neuron signs

AND

1.3.2 Bulbar signs

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 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
- 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

Approval Criteria

1 - The prescriber maintains and provides chart documentation of the patient's evaluation, including both of the following [6, 50, 52, 75, O]:

1.1 Findings of interval examination including neurological deficits incurred

AND

1.2 Assessment of disability (e.g., Expanded Disability Status Score [EDSS], Functional Systems Score [FSS], Multiple Sclerosis Functional Composie [MSFC], Disease Steps [DS])

AND

2 - Stable or improved disability score (e.g., EDSS, FSS, MSFC, DS) [6, 50, 52, 75]

AND

3 - Documentation of decreased number of relapses since starting immune globulin therapy [6, 50, 52, 75]

AND

4 - Diagnosis continues to be the relapsing-remitting form of MS (RRMS)

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]
Approval Length	12 month(s)
Guideline Type	Non Formulary

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
- Gammaplex
- Gamunex-C
- Privigen

Product Name: Asceniv, Panzyga	
Diagnosis	Myasthenia Gravis Exacerbation (off-label) [45-49]
Approval Length	3 month(s)
Guideline Type	Non Formulary

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

Approval Criteria

1 - Diagnosis of stiff-person syndrome [55, 83, 84]

AND

2 - Trial and failure, contraindication or intolerance to GABAergic medication (e.g., baclofen, benzodiazepines) [55, 83, 84]

AND

3 - Trial and failure, contraindication or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids) [55, 83, 84]

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: Intravenous immune globulin (IVIG)	
Diagnosis	Stiff Person Syndrome (off-label) [53]
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	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

Approval Criteria

1 - One of the following diagnoses [29]:

- Dermatomyositis
- Polymyositis

AND

2 - Trial and failure, contraindication, or intolerance to immunosuppressive therapy (e.g., azathioprine, corticosteroids, cyclophosphamide, methotrexate) [29, Q]

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: 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

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

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: Intravenous immune globulin (IVIG)	
Diagnosis	Guillain-Barre Syndrome (off-label) [38-40]
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	Guillain-Barre Syndrome (off-label) [38-40]
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Guillain-Barre Syndrome

AND

2 - Patients with severe disease requiring aid to walk [40, E]

AND

3 - Onset of neuropathic symptoms within the last four weeks [40, E]

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	Lambert-Eaton Myasthenic Syndrome (off-label) [41]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) [41]

AND

2 - History of failure, contraindication, or intolerance to immunomodulator monotherapy (e.g., azathioprine, corticosteroids) [81, 82]

AND

3 - Concomitant immunomodulator therapy (eg, azathioprine, corticosteroids), unless contraindicated, will be used for long-term management of LEMS [81, 82]

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: 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

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient requires prophylaxis for CMV infection following kidney transplantation

AND

1.1.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

OR

1.2 All of the following:

1.2.1 Patient requires prophylaxis for CMV infection following liver, heart, lung, or pancreas transplantation

AND

1.2.2 Patient is CMV- seronegative and organ donor is CMV-seropositive

AND

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

Product Name: Varizig	
Diagnosis	Varicella
Approval Length	1 Dose
Guideline Type	Prior Authorization

Approval Criteria

1 - For passive immunization or post exposure-prophylaxis of varicella

AND

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)

AND

3 - Prescribed immune globulin is being used intramuscularly

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]

4 . References

1. Gammagard Liquid Prescribing Information. Baxalta US Inc. Lexington, MA. March 2021.
2. Cuvitru Prescribing Information. Baxalta US Inc. Lexington, MA. September 2021.
3. Carimune NF Prescribing Information. CSL Behring LLC. Kankakee, IL. May 2018.
4. Varizig Prescribing Information. Saol Therapeutics Inc. Roswell, GA. September 2021.
5. Gammagard S/D Prescribing Information. Baxalta US Inc. Lexington, MA. March 2021.
6. 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 March 1, 2023.
7. Newburger JW, Takahashi M, Beiser AS, et al. A single intravenous infusion of gamma globulin as compared with four infusions in the treatment of acute Kawasaki syndrome. N Engl J Med. 1991;324:1633-9.
8. Newburger JW, Takahashi M, Burns JC, et al. The treatment of Kawasaki syndrome with intravenous gamma globulin. N Engl J Med. 1986;315:341-7.
9. Terai M, Shulman ST. Prevalence of coronary artery abnormalities in Kawasaki disease is highly dependent on gamma globulin dose but independent of salicylate dose. J Pediatr 1997;131:888–93.
10. Cooperative Group for the Study of Immunoglobulin in Chronic Lymphocytic Leukemia: Intravenous immunoglobulin for the prevention of infection in chronic lymphocytic leukemia: a randomized, controlled trial. N Engl J Med. 1988;319:902-907.

11. Oscier D, Fegan C, Hillmen P, et al. Guidelines on the diagnosis and management of chronic lymphocytic leukaemia. Br J Haematol. 2004;125:294-317.
12. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma v2.2023. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed March 1, 2023.
13. Gamm H, Huber C, Chapel H, et al. Intravenous immune globulin in chronic lymphocytic leukaemia. Clin Exp Immunol. 1994;97 Suppl 1:17-20.
14. Molica S, Musto P, Chiurazzi F, et al. Prophylaxis against infections with low-dose intravenous immunoglobulins (IVIG) in chronic lymphocytic leukemia. Results of a cross-over study. Haematologica. 1996;81:121-126.
15. Koller H, Kieseier BC, Jander S, et al. Chronic inflammatory demyelinating polyneuropathy. N Engl J Med. 2005;352(13):1343-56.
16. Saperstein DS, Katz JS, Amato AA, et al. Clinical spectrum of chronic acquired demyelinating polyneuropathies. Muscle Nerve. 2001;24:311-24.
17. Hughes R, Bensa S, Willison H, et al. Inflammatory Neuropathy Cause and Treatment (INCAT) Group. Randomized controlled trial of intravenous immunoglobulin versus oral prednisolone in chronic inflammatory demyelinating polyradiculoneuropathy. Ann Neurol. 2001;50:195-201.
18. Mendell JR, Barohn RJ, Freimer ML, et al. Working Group on Peripheral Neuropathy. Randomized controlled trial of IVIg in untreated chronic inflammatory demyelinating polyradiculoneuropathy. Neurology. 2001;56:445-9.
19. Dyck PJ, Litchy WJ, Kratz KM, et al. A plasma exchange versus immune globulin infusion trial in chronic inflammatory demyelinating polyradiculoneuropathy. Ann Neurol. 1994;36:838-45.
20. van Schaik IN, Winer JB, de Haan R, et al. Intravenous immunoglobulin for chronic inflammatory demyelinating polyradiculoneuropathy: a systematic review. Lancet Neurol. 2002;1:491-8.
21. Centers for Disease Control and Prevention; Infectious Disease Society of America; American Society of Blood and Marrow Transplantation. Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. MMWR Recomm Rep. 2000;49(RR-10):1-125.
22. Sullivan KM, Kopecky KJ, Jocom J, et al. Immunomodulatory and antimicrobial efficacy of intravenous immunoglobulin in bone marrow transplantation. N Engl J Med. 1990;323:705-12.
23. Sullivan KM, Storek J, Kopecky K, et al. A controlled trial of long-term administration of intravenous immunoglobulin to prevent late infection and chronic graft-vs.-host disease after marrow transplantation: clinical outcome and effect on subsequent immune recovery. Biol Blood Marrow Transplant. 1996;2:44-53.
24. Sokos DR, Berger M, Lazarus HM. Intravenous immunoglobulin: appropriate indications and uses in hematopoietic stem cell transplantation. Biol Blood Marrow Transplant. 2002;8:117-30.
25. Dalakas MC, Illa I, Dambrosia JM, et al. A controlled trial of high-dose intravenous immune globulin infusions as treatment for dermatomyositis. N Engl J Med. 1993;329:1993-2000.
26. Danieli M, Malcangi G, Palmieri C, et al. Cyclosporin A and Intravenous Immunoglobulin Treatment in Polymyositis/Dermatomyositis. Ann Rheum Dis. 2002;61;37-41.
27. Cherin P, Herson S, Wechsler B, et al. Efficacy of intravenous gammaglobulin therapy in chronic refractory polymyositis and dermatomyositis: an open study with 20 adult patients. Am J Med. 1991;91:162-8.
28. Lang BA, Laxer RM, Murphy G, et al. Treatment of dermatomyositis with intravenous gammaglobulin. Am J Med. 1991;91:169–72.

29. Drake LA, Dinehart SM, Farmer ER, et al. Guidelines of care for dermatomyositis. American Academy of Dermatology. J Am Acad Dermatol. 1996;34:824-9.
30. van Schaik IN, van den Berg LH, de Haan R, et al. Intravenous immunoglobulin for multifocal motor neuropathy. Cochrane Database Syst Rev. 2005;(2):CD004429.
31. Federico P, Zochodne DW, Hahn AF, et al. Multifocal motor neuropathy improved by IVIg: randomized, double-blind, placebo-controlled study. Neurology. 2000;55:1256-62.
32. Van den Berg LH, Franssen H, Wokke JH. The long-term effect of intravenous immunoglobulin treatment in multifocal motor neuropathy. Brain. 1998;121:421-8.
33. Leger JM, Chassande B, Musset L, et al. Intravenous immunoglobulin therapy in multifocal motor neuropathy: a double-blind, placebo-controlled study. Brain. 2001;124:145-53.
34. Van den Berg LH, Kerkhoff H, Oey PL, et al. Treatment of multifocal motor neuropathy with high dose intravenous immunoglobulins: a double blind, placebo controlled study. J Neurol Neurosurg Psychiatry. 1995;59:248-52.
35. Mofenson LM, Moye J Jr, Bethel J, et al. Prophylactic intravenous immunoglobulin in HIV-infected children with CD4+ counts of 0.20 x 10(9)/L or more. Effect on viral, opportunistic, and bacterial infections. The National Institute of Child Health and Human Development Intravenous Immunoglobulin Clinical Trial Study Group. JAMA. 1992;268:483-8.
36. Mofenson LM, Moye J Jr, Korelitz J, et al. Crossover of placebo patients to intravenous immunoglobulin confirms efficacy for prophylaxis of bacterial infections and reduction of hospitalizations in human immunodeficiency virus-infected children. The National Institute of Child Health and Human Development Intravenous Immunoglobulin Clinical Trial Study Group. Pediatr Infect Dis J. 1994;13:477-84.
37. Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf. Accessed March 1, 2023.
38. Plasma Exchange/Sandoglobulin Guillain-Barre Syndrome Trial Group. Randomised trial of plasma exchange, intravenous immunoglobulin, and combined treatments in Guillain-Barre syndrome. Lancet. 1997;349:225-30.
39. van der Meche FG, Schmitz PI. A randomized trial comparing intravenous immune globulin and plasma exchange in Guillain-Barre syndrome. Dutch Guillain-Barre Study Group. N Engl J Med. 1992;326:1123-9
40. Hughes RA, Wijdicks EF, Barohn R, et al. Quality Standards Subcommittee of the American Academy of Neurology. Practice parameter: immunotherapy for Guillain-Barre syndrome: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2003;61:736-40.
41. Bain PG, Motomura M, Newsom-Davis J, et al. Effects of intravenous immunoglobulin on muscle weakness and calcium-channel autoantibodies in the Lambert-Eaton myasthenic syndrome. Neurology. 1996;47:678-83.
42. Winston DJ, Antin JH, Wolff SN, et al. A multicenter, randomized, double-blind comparison of different doses of intravenous immunoglobulin for prevention of graft-versus-host disease and infection after allogeneic bone marrow transplantation. Bone Marrow Transplant. 2001;28:187-96.
43. Cordonnier C, Chevret S, Legrand M, et al. GREFIG Study Group. Should immunoglobulin therapy be used in allogeneic stem-cell transplantation? A randomized, double-blind, dose effect, placebo-controlled, multicenter trial. Ann Intern Med. 2003 1;139:8-18.

44. Immune Globulin. In: McEvoy GK, ed. AHFS 2004 Drug Information. Bethesda, MD: American Society of Health-System Pharmacists; 2004:3154-3164.
45. Gajdos P, Chevret S, Clair B, et al. Clinical trial of plasma exchange and high-dose intravenous immunoglobulin in myasthenia gravis. Myasthenia Gravis Clinical Study Group. Ann Neurol. 1997;41:789-96.
46. Wegner B, Ahmed I. Intravenous immunoglobulin monotherapy in long-term treatment of myasthenia gravis. Clin Neurol Neurosurg. 2002;105:3-8.
47. Jongen JL, van Doorn PA, van der Meche FG. High-dose intravenous immunoglobulin therapy for myasthenia gravis. J Neurol. 1998;245:26-31.
48. Gajdos P, Chevret S, Toyka K. Intravenous immunoglobulin for myasthenia gravis. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD002277.
49. Sharshar T, Chevret S, Mazighi M, et al. Validity and reliability of two muscle strength scores commonly used as endpoints in assessing treatment of myasthenia gravis. J Neurol. 2000;247:286-90.
50. Fazekas F, Deisenhammer F, Strasser-Fuchs S, et al. Randomised placebo-controlled trial of monthly intravenous immunoglobulin therapy in relapsing-remitting multiple sclerosis. Austrian Immunoglobulin in Multiple Sclerosis Study Group. Lancet. 1997;349:589-93.
51. Achiron A, Gabbay U, Gilad R, et al. Intravenous immunoglobulin treatment in multiple sclerosis. Effect on relapses. Neurology. 1998;50:398-402.
52. Goodin DS, Frohman EM, Garmany GP Jr, et al. Disease modifying therapies in multiple sclerosis: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the MS Council for Clinical Practice Guidelines. Neurology 2002;58:169-78.
53. Dalakas MC, Fujii M, Li M, et al. High-dose intravenous immune globulin for stiff-person syndrome. N Engl J Med. 2001;345:1870-6.
54. Newburger JW, Takahashi M, Gerber MA, et al. Diagnosis, treatment, and long-term management of Kawasaki disease: a statement for health professionals from the Committee on Rheumatic Fever, Endocarditis and Kawasaki Disease, Council on Cardiovascular Disease in the Young, American Heart Association. Circulation. 2004;110:2747-71.
55. Hughes RA, Bouche P, Cornblath DR, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the EFNS and PNS. Eur J Neurol 2006 Apr;13(4):326-32.
56. Gammaplex 10% Prescribing Information. Bio Products Laboratory Ltd. Elstree, UK. November 2021.
57. Gamastan Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. February 2018.
58. National Institute of Neurological Disorders and Stroke. Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Available at: https://www.ninds.nih.gov/health-information/disorders/chronic-inflammatory-demyelinating-polyneuropathy-cidp. Accessed March 3, 2023.
59. Drachman DB. Myasthenia Gravis. N Engl J Med. 1994;1797-1810.
60. Cytogam Prescribing Information. CSL Behring LLC. King of Prussia, PA. May 2020.
61. Hizentra Prescribing Information. CSL Behring LLC. Kankakee, IL. April 2022.
62. Privigen Prescribing Information. CSL Behring LLC. Kankakee, IL. March 2022.
63. Octagam 10% Prescribing Information. Octapharma USA Inc. Paramus, NJ. April 2022.
64. Apostolski, ES, Doorn PV, Gilhus NE, et al. EFNS Task Force. EFNS guidelines for the use of intravenous immunoglobulin in treatment of neurological diseases. European Journal of Neurology 2008; 15:893-908.

65. Flebogamma 5% DIF Prescribing Information. Instituto Grifols, S.A. Barcelona, Spain. September 2019.
66. Flebogamma 10% DIF Prescribing Information. Instituto Grifols, S.A. Barcelona, Spain. September 2019.
67. Gammaplex 5% Prescribing Information. Bio Products Laboratory Ltd. Elstree, UK. November 2021.
68. Gamunex-C Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. January 2020.
69. Gammaked Prescribing Information. Grifols Therapeutics LLC. Research Triangle Park, NC. January 2020.
70. Bivigam Prescribing Information. ADMA Biologics, Inc. Boca Raton, FL. December 2022.
71. Octagam 5% Prescribing Information. Octapharma USA Inc. Paramus, NJ. April 2022.
72. Orange JS, Hossny EM, Weiler CR, et al. Use of intravenous immunoglobulin in human disease: a review of evidence by members of the Primary Immunodeficiency Committee of the American Academy of Allergy, Asthma and Immunology. J Allergy Clin Immunol. 2006;117:S525-S553.
73. Bonilla FA, Bernstein L, Khan DA, et. al. Practice parameter for the diagnosis and management of primary immunodeficiency. Ann Allergy Asthma Immunol. 2005;94(suppl):S1-S63.
74. Patwa HS, Chaudhry V, Katzberg H, et al. Evidence-based guideline: intravenous immunoglobulin in the treatment of neuromuscular disorders: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2012 Mar 27;78(13):1009-15.
75. AHFS Drug Information/Lexi-Comp Online [internet database]. Hudson, OH. Lexi-Comp, Inc. Updated periodically. Available by subscription at: http://online.lexi.com/. Accessed March 1, 2023.
76. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society--first revision. J Peripher Nerv Syst. 2010 Dec;15(4):295-301. doi: 10.1111/j.1529-8027.2010.00290.x.
77. Van den Bergh PY, Hadden RD, Bouche P, et al. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of chronic inflammatory demyelinating polyradiculoneuropathy: report of a joint task force of the European Federation of Neurological Societies [trunc]. Eur J Neurol 2010 Mar;17(3):356-63.
78. Oscier D, Fegan C, Hillmen P, et al. Guidelines on the diagnosis and management of chronic lymphocytic leukaemia. Br J Haematol. 2004;125:294-317.
79. Centers for Disease Control and Prevention. Guidelines for the Prevention and Treatment of Opportunistic Infections Among HIV-Exposed and HIV-Infected Children. MMWR 2009;58(No. RR-11):11-12.
80. Yap PL. Does intravenous immune globulin have a role in HIV-infected patients? Clin Exp Immunol. 1994 Jul;97 Suppl 1:59-67.
81. Maddison P. Treatment in Lambert-Eaton myasthenic syndrome. Ann N Y Acad Sci. 2012 Dec;1275:78-84. doi: 10.1111/j.1749-6632.2012.06769.x.
82. Sanders DB. Lambert-Eaton myasthenic syndrome: diagnosis and treatment. Ann N Y Acad Sci. 2003 Sep;998:500-8.
83. McKeon A, Robinson MT, McEvoy KM, et al. Stiff-man syndrome and variants: clinical course, treatments, and outcomes. Arch Neurol. 2012 Feb;69(2):230-8. doi: 10.1001/archneurol.2011.991.

84. Levy LM, Dalakas MC, Floeter MK. The stiff-person syndrome: an autoimmune disorder affecting neurotransmission of gamma-aminobutyric acid. Ann Intern Med. 1999 Oct 5;131(7):522-30.
85. Stasi R, Evangelista ML, Stipa E, et al. Idiopathic thrombocytopenic purpura: current concepts in pathophysiology and management. Thrombosis and Haemostasis 2008;99(1):4-13.
86. Per clinical consult with neurologist, July 23, 2013.
87. Per clinical consult with neurologist, August 15, 2013.
88. Joint Task Force of the EFNS and the PNS. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Report of a joint task force of the European Federation of Neurological Societies and the Peripheral Nerve Society--first revision. J Peripher Nerv Syst. 2010 Dec;15(4):295-301. doi: 10.1111/j.1529-8027.2010.00290.x.
89. Panzyga Prescribing Information. Octapharma USA, Inc. Paramus, NJ. March 2021.
90. Cutaquig Prescribing Information. Octapharma USA, Inc. Paramus, NJ. November 2021.
91. Xembify Prescribing Information. Grifols Therapeutic LLC. Research Triangle Park, NC. August 2020.
92. Asceniv Prescribing Information. ADMA Biologics. Boca Raton, FL. April 2019.

5 . Revision History

Date	Notes
10/26/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Increlex (mecasermin [rDNA origin])

Prior Authorization Guideline

Guideline ID	GL-135710
Guideline Name	Increlex (mecasermin [rDNA origin])

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/4/2006
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: Increlex (mecasermin [rDNA origin]) injection
Severe Primary IGF-1 deficiency (Primary IGFD) Indicated for the treatment of growth failure in pediatric patients 2 years of age and older with severe primary IGF-1 deficiency (Primary IGFD) or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. Severe Primary IGFD is defined by: height standard deviation score less than or equal to -3.0, basal IGF-1 standard deviation score less than or equal to -3.0, and normal or elevated GH. Limitations of use: Increlex is not a substitute to GH for approved GH indications. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids.

2 . Criteria

Product Name: Increlex

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

Approval Criteria

1 - One of the following: [A]

1.1 All of the following:

1.1.1 Diagnosis of severe primary IGF-1 deficiency [3]

AND

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.

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.

3 . 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]

4 . References

1. Increlex Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. October 2023.
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 November 1, 2023.

5 . Revision History

Date	Notes
11/1/2023	Annual Review, no changes.

Prior Authorization Guideline

Guideline ID	GL-136047
Guideline Name	Infliximab – PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/15/2009
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 12/16/2020 ; 05/20/2021 ; 08/19/2021 ; 02/17/2022 ; 08/18/2022 ; 10/19/2022 ; 08/17/2023 ; 8/17/2023

1 . Indications

Drug Name: Remicade (infliximab), Infliximab, Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (Infliximab-abda)
Rheumatoid Arthritis (RA) 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. **Psoriatic Arthritis (PsA)** 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 (PsO)** 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. **Ankylosing Spondylitis (AS)** Indicated for reducing signs and symptoms in patients with active ankylosing spondylitis.

Crohn's Disease (CD) 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 (UC) 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.

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	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 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 - Used in combination with methotrexate

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 alread y been tried in the past, and the patient should not be made to try a thi rd 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 - 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

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	6 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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 - Used in combination with methotrexate

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, 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 alread y been tried in the past, and the patient should not be made to try a thi rd infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
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 [4]:

- 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 - 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 - 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, pruritus, inflammation) from baseline
- Reduction in the body surface area (BSA) involvement from baseline

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Psoriatic Arthritis (PsA)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of active PsA

AND

2 - One of the following [4]:

- 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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 (PsO)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- 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 [6]:

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

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy as evidenced by ONE of the following [1, 5]

- 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 (PsO)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2 - One of the following [5]:

- Greater than or equal to 3% body surface area 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 [6]:

- 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 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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	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 [7]

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 - Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for least one of the following [1, 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: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ankylosing Spondylitis (AS)
Approval Length	6 month(s)
Guideline Type	Non Formulary

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 NSAIDs (e.g., ibuprofen, naproxen) at maximally tolerated doses [7]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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 (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- 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 (CDAI) greater than 220

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 [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

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	Crohn's Disease (CD) or Fistulizing Crohn's Disease
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, 8, 9]:

- 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

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Crohn's Disease (CD) or Fistulizing Crohn's Disease
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Moderately to severely active Crohn's disease
- Fistulizing Crohn's disease

AND

2 - One of the following [8, 9]:

- 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 (CDAI) greater than 220

AND

3 - Prescribed by or in consultation with a gastroenterologist

AND

4 - 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 [8, 9]:

- 6-mercaptopurine
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

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, 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	Ulcerative Colitis (UC)
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 - One of the following [10, 11]:

- 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 [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine

- Corticosteroids (e.g., prednisone)

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 alread y been tried in the past, and the patient should not be made to try a thi rd infliximab product.

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
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, 10, 11]:

- 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

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Ulcerative Colitis (UC)
Approval Length	6 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [10, 11]:

- 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 - 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 [10, 11]:

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

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, 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] [12-15]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of sarcoidosis

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, cyclophosphamide, or 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] [12-15]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to infliximab therapy

Product Name: Avsola, Inflectra, Infliximab, Remicade, Renflexis	
Diagnosis	Sarcoidosis [Off-label] [12-15]
Approval Length	6 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, cyclophosphamide, or azathioprine)

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, 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 . References

1. Remicade Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 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. 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. 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.
6. 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.

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. 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.
9. 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.
10. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019;114:384-413.
11. 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.
12. DRUGDEX System [Internet database]. Greenwood Village, Colo: Truven Health Analytics. Updated periodically. Accessed July 7, 2020.
13. 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.
14. 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.
15. Per clinical consult with dermatologist. June 26, 2019.
16. Inflectra prescribing information. Hospira. Lake Forest, IL. March 2022.
17. Renflexis Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. January 2022.
18. Avsola Prescribing Information. Amgen Inc. Thousand Oaks, CA. September 2021.
19. Infliximab Prescribing Information. Janssen Biotech, Inc. Horsham, PA. October 2021.

4 . Revision History

Date	Notes
11/7/2023	Updated effective date.

Inlyta (axitinib)

Prior Authorization Guideline

Guideline ID	GL-127641
Guideline Name	Inlyta (axitinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	8/21/2012
P&T Revision Date:	07/17/2019 ; 07/15/2020 ; 07/21/2021 ; 05/19/2022 ; 08/18/2022 ; 05/18/2023 ; 7/19/2023

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:

2.1 Used as first-line treatment in combination with one of the following for clear cell renal cell carcinoma**: [2]

- avelumab*
- pembrolizumab*

OR

2.2 Used after failure of one prior systemic therapy (e.g., chemotherapy) for clear cell renal cell carcinoma** [2]

OR

2.3 One of the following:

2.3.1 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

2.3.2 For continuation of prior therapy

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.

4 . Revision History

Date	Notes
7/6/2023	Updated criteria and removed specialist requirement

Interstitial Lung Disease (ILD) Agents

Prior Authorization Guideline

Guideline ID	GL-135555
Guideline Name	Interstitial Lung Disease (ILD) Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/4/2014
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 12/16/2020 ; 11/18/2021 ; 06/15/2022 ; 09/21/2022 ; 11/17/2022 ; 03/15/2023 ; 08/17/2023 ; 11/16/2023

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 adults with idiopathic pulmonary fibrosis (IPF). **Systemic Sclerosis-associated Interstitial Lung Disease** Indicated to slow the rate of decline in pulmonary function in adult 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

Approval Criteria

1 - Diagnosis of idiopathic pulmonary fibrosis (IPF) as documented by both of the following: [3]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

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

OR

1.2.2 In patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF

AND

2 - For brand Esbriet capsules and tablets, trial and failure or intolerance to generic pirfenidone

AND

3 - Prescribed by or in consultation with a pulmonologist

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

Approval Criteria

1 - Diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) as documented by the following: [5-6]

1.1 Exclusion of other known causes of interstitial lung disease (ILD) (e.g., domestic and occupational environmental exposures, connective tissue disease, drug toxicity)

AND

1.2 One of the following:

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

OR

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - For brand Esbriet capsules and tablets, trial and failure or intolerance to generic pirfenidone

Product Name: Ofev	
Diagnosis	All Indications
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. Esbriet prescribing information. Genentech, Inc. South San Francisco, CA. February 2023.
2. Ofev prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2022.
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, Rochwerg 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. March 2023.

4 . Revision History

Date	Notes
10/27/2023	Annual review: No criteria changes. Updated indications, references.

Jakafi (ruxolitinib)

Prior Authorization Guideline

Guideline ID	GL-137428
Guideline Name	Jakafi (ruxolitinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/21/2012
P&T Revision Date:	08/15/2019 ; 03/18/2020 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 03/15/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Jakafi (ruxolitinib)
Myelofibrosis Indicated for treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. **Polycythemia Vera** Indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **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. **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.

2 . Criteria

Product Name: Jakafi	
Diagnosis	Myelofibrosis
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Primary myelofibrosis
- Post-polycythemia vera myelofibrosis
- Post-essential thrombocythemia myelofibrosis

Product Name: Jakafi	
Diagnosis	Polycythemia Vera
Approval Length	8 Months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of polycythemia vera [1]

AND

2 - Trial and failure, contraindication, or intolerance to hydroxyurea [1]

Product Name: Jakafi	
Diagnosis	Myelofibrosis, Polycythemia Vera
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to 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

Product Name: Jakafi	
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 - Patient is 12 years of age or older

AND

3 - Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.)

Product Name: Jakafi	
Diagnosis	Chronic Graft Versus Host Disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

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.

5 . Revision History

Date	Notes
12/6/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Jevtana (cabazitaxel)

Prior Authorization Guideline

Guideline ID	GL-126910
Guideline Name	Jevtana (cabazitaxel)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/15/2011
P&T Revision Date:	03/17/2021 ; 03/16/2022 ; 7/19/2023

1 . Indications

Drug Name: Jevtana (cabazitaxel)
Prostate Cancer Indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

2 . Criteria

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

Approval Criteria

1 - All of the following:

1.1 Diagnosis of metastatic castration-resistant prostate cancer

AND

1.2 Used in combination with prednisone

AND

1.3 Patient has been previously treated with a docetaxel-containing regimen

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

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Jevtana Prescribing Information. Sanofi-Aventis U.S. LLC, Bridgewater, NJ. February 2021.

4 . Revision History

Date	Notes

6/22/2023	Removed specialist requirement

Kalydeco (ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-136635
Guideline Name	Kalydeco (ivacaftor)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/21/2012
P&T Revision Date:	04/15/2020 ; 11/12/2020 ; 02/18/2021 ; 02/17/2022 ; 02/16/2023 ; 07/19/2023 ; 07/19/2023 ; 12/13/2023

1 . Indications

Drug Name: Kalydeco (ivacaftor)
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.

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.

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

Approval Criteria

1 - Patient demonstrates 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]

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 KALYDE				
*711+3A→G **	*F311del*	*I148T*	*R75Q*	*S589N*
*2789+5G→A **	*F311L*	*I175V*	*R117C **	*S737F*
*3272-26A→G **	*F508C*	*I807M*	*R117G*	*S945L **
*3849+10kbC→T **	*F508C;S1251N †*	*I1027T*	*R117H **	*S977F **
A120T	*F1052V*	*I1139V*	*R117L*	*S1159F*
A234D	*F1074L*	*K1060T*	*R117P*	*S1159P*
A349V	*G178E*	*L206W **	*R170H*	*S1251N **
*A455E **	*G178R **	*L320V*	*R347H **	*S1255P **
A1067T	*G194R*	*L967S*	*R347L*	*T338I*
D110E	*G314E*	*L997F*	*R352Q **	*T1053I*
D110H	*G551D **	*L1480P*	*R553Q*	*V232D*
D192G	*G551S **	*M152V*	*R668C*	*V562I*
*D579G **	*G576A*	*M952I*	*R792G*	*V754M*
D924N	*G970D*	*M952T*	*R933G*	*V1293G*
*D1152H **	*G1069R*	*P67L **	*R1070Q*	*W1282R*
D1270N	*G1244E **	*Q237E*	*R1070W **	*Y1014C*
E56K	*G1249R*	*Q237H*	*R1162L*	*Y1032C*

E193K	*G1349D **	*Q359R*	*R1283M*
E822K	*H939R*	*Q1291R*	*S549N **
*E831X **	*H1375P*	*R74W*	*S549R **

** 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.

6 . Revision History

Date	Notes
11/23/2023	Addition of Kalydeco 5.8mg granules as target.

Kanuma (sebelipase alfa)

Prior Authorization Guideline

Guideline ID	GL-127503
Guideline Name	Kanuma (sebelipase alfa)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Kanuma (sebelipase alfa)
Lysosomal Acid Lipase (LAL) deficiency Indicated for the treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of lysosomal acid lipase deficiency (LAL-D, Wolman Disease, Cholesteryl ester storage disease) [B]

AND

2 - Diagnosis was confirmed by one of the following: [A]

2.1 Enzymatic blood test (e.g., dried blood spot test) demonstrating a deficiency of LAL enzyme activity

OR

2.2 Genetic testing for mutations in the lipase A, lysosomal acid type (LIPA) gene

AND

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

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

Product Name: Kanuma	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy (e.g., reduction in LDL, triglycerides, AST or ALT, increase in HDL, reduction in liver fat content)

AND

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

- A specialist experienced in the treatment of inborn errors of metabolism
- Gastroenterologist
- Lipidologist

3 . Endnotes

A. Due to similar clinical presentations, LAL-D is often misdiagnosed as familial defective apolipoprotein B (ApoB) deficiency, heterozygous familial hypercholesterolemia (HeFH), familial combined hyperlipidemia (FCH), or polygenic hypercholesterolaemia [3]. A diagnosis of LAL-D can be confirmed by identification of a LIPA mutation or a deficient LAL enzyme in peripheral blood leukocytes, fibroblasts, or dried blood spots. A biopsy and/or radiographic findings may help support a LAL-D diagnosis, however these are not considered diagnostic. [2,3]
B. LAL deficiency is sub-classified as Wolman disease in infants and cholesteryl ester storage disease (CESD) in children and adults. [4]

4 . References

1. Kanuma prescribing information, Alexion Pharmaceuticals. Cheshire, CT. November 2021.
2. Burton BK, Balwani M, Feillet F, et al. A Phase 3 Trial of Sebelipase Alfa in Lysosomal Acid Lipase Deficiency. N Engl J Med. 2015;373(11):1010-20.
3. Reiner, Guardamagna, Nair, et al. Lysosomal acid lipase deficiency - an under-recognized cause of dyslipidaemia and liver dysfunction. Atherosclerosis. 2014;235(1): 21-30.
4. Strebinger G, Müller E, Feldman A, Aigner E. Lysosomal acid lipase deficiency - early diagnosis is the key. Hepat Med. 2019 May 23;11:79-88.

5 . Revision History

Date	Notes
7/3/2023	Annual review: No criteria changes. Updated initial auth duration to 1 2 months and reauth duration to 24 months.

Keveyis (dichlorphenamide)

Prior Authorization Guideline

Guideline ID	GL-129278
Guideline Name	Keveyis (dichlorphenamide)

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	11/18/2015
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 01/18/2023 ; 03/15/2023 ; 8/17/2023

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

5 . Revision History

Date	Notes
8/2/2023	Annual review - no criteria changes

Kineret (anakinra)

Prior Authorization Guideline

Guideline ID	GL-136311
Guideline Name	Kineret (anakinra)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/28/2002
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 02/17/2022 ; 10/19/2022 ; 12/14/2022 ; 02/16/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Kineret (anakinra)
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. **Cryopyrin-Associated Periodic Syndromes (CAPS): Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]** Indicated for the treatment of Neonatal-Onset Multisystem Inflammatory Disease (NOMID). **Deficiency of Interleukin-1 Receptor Antagonist (DIRA)** Indicated for the treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA). **Off Label Uses: Systemic Juvenile Idiopathic Arthritis (SJIA)** Has been used for the treatment of systemic juvenile idiopathic arthritis. [7]

2 . Criteria

Product Name: Kineret	
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 All 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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Kineret	
Diagnosis	Rheumatoid Arthritis (RA)
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

Product Name: Kineret	
Diagnosis	Neonatal-Onset Multisystem Inflammatory Disease (NOMID) [A]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of neonatal-onset multisystem inflammatory disease (NOMID)

AND

2 - Diagnosis of NOMID has been confirmed by one of the following: [5-6, B]

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

OR

2.2 Both of the following:

2.2.1 Two of the following clinical symptoms:

- 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)

AND

2.2.2 Elevated acute phase reactants (e.g., erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA])

AND

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

- 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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Kineret	
Diagnosis	Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA)

Product Name: Kineret	
Diagnosis	Systemic Juvenile Idiopathic Arthritis (SJIA) (Off-Label)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of active systemic juvenile idiopathic arthritis [7]

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 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [7]:

- 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.

5 . Revision History

Date	Notes

11/14/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Korlym (mifepristone)

Prior Authorization Guideline

Guideline ID	GL-131822
Guideline Name	Korlym (mifepristone)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 9/20/2023

1 . Indications

Drug Name: Korlym (mifepristone)
Hyperglycemia in Patients with Endogenous Cushing's Syndrome and Type 2 Diabetes Mellitus Indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Limitations of use: Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome.

2 . Criteria

Product Name: Korlym	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids) [A]

AND

2 - One of the following:

- 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: [1,2]

- 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 [1]

Product Name: Korlym

Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of one of the following:

- Patient has improved glucose tolerance while on therapy
- Patient has stable glucose tolerance while on therapy

3 . 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]

4 . References

1. Korlym prescribing information. Corcept Therapeutics Inc. Menlo Park, CA. November 2019.
2. Nieman LK, Biller BM, Findling JW, et al. Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2015;100(8):2807-2831.

5 . Revision History

Date	Notes
8/28/2023	2023 Annual Review

Koselugo (selumetinib)

Prior Authorization Guideline

Guideline ID	GL-131180
Guideline Name	Koselugo (selumetinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/17/2020
P&T Revision Date:	06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 6/21/2023

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

Product Name: Koselugo	
Diagnosis	Neurofibromatosis Type 1
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 . 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. December 2021.
2. Per clinical consult with oncologist, May 27, 2020.

5 . Revision History

Date	Notes
8/21/2023	Removed prescriber requirement

Kyprolis (carfilzomib)

Prior Authorization Guideline

Guideline ID	GL-134239
Guideline Name	Kyprolis (carfilzomib)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	10/18/2019 ; 10/21/2020 ; 10/20/2021 ; 02/17/2022 ; 08/18/2022 ; 10/19/2022 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Kyprolis (carfilzomib)
Multiple myeloma - combination therapy Indicated in combination with dexamethasone or with lenalidomide plus dexamethasone or daratumumab plus dexamethasone or daratumumab and hyaluronidase-fihj plus dexamethasone, or isatuximab plus dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy. **Multiple myeloma - monotherapy** Indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have received one or more lines of therapy.

2 . Criteria

Product Name: Kyprolis

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

Approval Criteria

1 - Diagnosis of multiple myeloma (MM)

AND

2 - Disease is relapsed or refractory

AND

3 - Patient has received at least one prior therapy for MM

Product Name: Kyprolis	
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. Kyprolis Prescribing Information. Onyx Pharmaceuticals, Inc. Thousand Oaks, CA. June 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Multiple Myeloma v5.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/myeloma_blocks.pdf. Accessed July 20, 2022.

4 . Revision History

Date	Notes
10/3/2023	Annual Review - No criteria changes

Lenvima (lenvatinib)

Prior Authorization Guideline

Guideline ID	GL-127643
Guideline Name	Lenvima (lenvatinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/14/2015
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/12/2020 ; 09/15/2021 ; 11/18/2021 ; 08/18/2022 ; 11/17/2022 ; 05/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Lenvima (lenvatinib)
Differentiated Thyroid Carcinoma Indicated for the treatment of patients with locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer (DTC). **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. **Hepatocellular Carcinoma** Indicated for the treatment of patients with unresectable hepatocellular carcinoma (HCC). **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

2 . Criteria

Product Name: Lenvima	
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]

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:

2.1 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

2.2 Both of the following*: [4]

- Used as first-line treatment for clear cell renal cell carcinoma
- Used in combination with Keytruda (pembrolizumab)

OR

2.3 One of the following:

2.3.1 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

2.3.2 For continuation of prior therapy

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

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

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.

5 . Revision History

Date	Notes
7/6/2023	Updated criteria and removed specialist requirement

Lonsurf (trifluridine and tipiracil)

Prior Authorization Guideline

Guideline ID	GL-131817
Guideline Name	Lonsurf (trifluridine and tipiracil)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

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

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

AND

2 - One of the following:

2.1 Used as a single agent

OR

2.2 Used in combination with bevacizumab

AND

3 - Trial and failure, intolerance or contraindication to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI)

AND

4 - Trial and failure, intolerance or contraindication to an anti-VEGF therapy (e.g., Avastin [bevacizumab], Zaltrap [ziv-aflibercept])

AND

5 - One of the following:

5.1 Patient has RAS mutant tumors

OR

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.

4 . Revision History

Date	Notes
8/28/2023	2023 Annual Review

Lumizyme (alglucosidase alfa)

Prior Authorization Guideline

Guideline ID	GL-134224
Guideline Name	Lumizyme (alglucosidase alfa)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/5/2006
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 11/18/2021 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Lumizyme (alglucosidase alfa)
Pompe Disease Indicated for patients with Pompe disease [acid alpha-glucosidase (GAA) deficiency].

2 . Criteria

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of infantile-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3]

1.1 Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.)

AND

3 - Patient is less than or equal to 12 months of age

Product Name: Lumizyme	
Diagnosis	Infantile Onset Pompe Disease (IOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)

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

Approval Criteria

1 - Diagnosis of late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: [3, 5]

1.1 Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay

OR

1.2 Molecular genetic testing confirms mutations in the GAA gene

AND

2 - Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.) [A]

AND

3 - Patient is 1 year of age or older

Product Name: Lumizyme	
Diagnosis	Late Onset Pompe Disease (LOPD)
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. Consensus recommendation based on current clinical guidelines indicate that treatment should be started in patients with late onset Pompe disease when they become symptomatic and/or show signs of disease progression [3, 5].

4 . References

1. Lumizyme Prescribing Information. Genzyme Corporation. Cambridge, MA. May 2022.
2. Kronn DF, Day-Salvatore D, Hwu WL, et al. Management of Confirmed Newborn-Screened Patients With Pompe Disease Across the Disease Spectrum.
3. Kishani PS, Steiner RD, Bali, D. ACMG Practice Guideline. Pompe disease diagnosis and management guideline. Genet Med. 2006;8(5):267-88.
4. Diagnosing Pompe Disease (also known as Acid Maltase Deficiency). Available at: https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bk1vFinal10.pdf?la=en-US and https://www.pompe.com/-/media/EMS/Conditions/RareDiseases/Brands/pompe-us/hcp/PDF/SAUSPD18042050bj1vFinal10.pdf?la=en-US. Accessed May 12, 2020.
5. Barba-Romero MA, Barrot E, Bautista-Lorite J, et al. Clinical guidelines for late-onset Pompe disease. Rev Neurol 2012; 54 (8): 497-507.

5 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes t o clinical intent

Lynparza (olaparib)

Prior Authorization Guideline

Guideline ID	GL-127054
Guideline Name	Lynparza (olaparib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	03/18/2020 ; 07/15/2020 ; 03/17/2021 ; 03/16/2022 ; 05/19/2022 ; 10/19/2022 ; 03/15/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Lynparza (olaparib)
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 (gBRCAmor sBRCAm) 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. **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. **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.

Germline BRCA-mutated HER2-negative high risk early breast cancer Indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCA-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
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of breast cancer

Product Name: Lynparza	
Diagnosis	Pancreatic adenocarcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis pancreatic adenocarcinoma

Product Name: Lynparza	
Diagnosis	Metastatic castration-resistant prostate cancer (mCRPC)
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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 Accessed 3/7/2018

4 . Revision History

Date	Notes
7/21/2023	update guideline

Prior Authorization Guideline

Guideline ID	GL-135638
Guideline Name	Managed Administrative Biosimilars Policy - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/16/2023
P&T Revision Date:	05/18/2023 ; 07/19/2023 ; 09/20/2023 ; 09/20/2023 ; 10/18/2023 ; 11/16/2023

Note:

This guideline applies to nonpreferred biosimilars. For the following Tier 2 products: Humira, Amjevita, Cyltezo, Hyrimoz by Sandoz, and Brand Adalimumab-adaz, refer to the "Adalimumab" guideline for review.

1 . Indications

Drug Name: Abrilada (adalimumab-afzb), Amjevita (adalimumab-atto), Brand Adalimumab-adbm, Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Idacio (adalimumab-aacf), 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.

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

Drug Name: Yuflyma (adalimumab-aaty)

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.

2 . Criteria

Product Name: Abrilada*, Amjevita (Tier 3, Non-Preferred or NF)*, Brand Adalimumab-adbm*, Hadlima*, Hulio*, Brand Adalimumab-fkjp*, Hyrimoz (Tier 3, Non-Preferred or NF, Cordavis manufacturer)*, 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) • Amjevita (preferred adalimumab-atto product) (Tier 2) • Cyltezo (adalimumab-adbm) • Hyrimoz or Brand Adalimumab-adaz (Tier 2) **AND** **3** - Submission of medical records documenting why the covered products have not been effective	
Notes	Abrilada, Tier 3 Amjevita, Brand Adalimumab-adbm, Hadlima, Hulio, Brand Adalimumab-fkjp, Tier 3 Hyrimoz, Idacio, Yuflyma, and Yusimry are nonpreferred. Plan covers the following Tier 2 products: Humira, Amjevita, Cyltezo, Hyrimoz by Sandoz, and Brand Adalimumab-adaz. 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
Amjevita 10 mg/0.2 mL prefilled syringe	55513-413-01
Amjevita 20 mg/0.4 mL prefilled syringe	55513-411-01
Amjevita 40 mg/0.8 mL prefilled syringe	55513-410-01
Amjevita 40 mg/0.8 mL Prefilled SureClick Autoinjector	55513-400-01 55513-400-02
Cyltezo – all products	All Cyltezo NDCs
Humira – all products	All Humira NDCs
Hyrimoz – manufactured by Sandoz	61314-0473-20

	61314-0454-20 61314-0454-36 61314-0517-36 61314-0509-64 61314-0476-64 61314-0473-64 61314-0454-68 61314-0531-64
Brand Adalimumab-adaz – all products	All Brand Adalimumab-adaz NDCs
Nonpreferred Products – TIER 3	**NDC**
Abrilada – all products	All Abrilada NDCs
Amjevita 40 mg/0.8 mL Prefilled SureClick Autoinjector	72511-400-01 72511-400-02
Brand Adalimumab-adbm – all products	All Brand Adalimumab-adbm NDCs
Hadlima – all products	All Hadlima NDCs
Hulio – all products	All Hulio NDCs
Brand Adalimumab-fkjp – all products	All Brand Adalimumab-fkjp NDCs
Hyrimoz – manufactured by Cordavis	83457-0102-01 83457-0103-01 83457-0100-01 83457-0101-01 83457-0201-46 83457-0200-40 83457-0202-50 83457-0203-56
Idacio – all products	All Idacio NDCs
Yuflyma – all products	All Yuflyma NDCs

Yusimry – all products	All Yusimry NDCs	

4 . References

1. Abrilada Prescribing Information. Pfizer Inc. New York, NY. October 2023.
2. Amjevita Prescribing Information. Amgen Inc. Thousand Oaks, CA. August 2023.
3. Cyltezo Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. June 2023.
4. Hadlima Prescribing Information. Samsung Bioepis Co, Ltd; Organon LLC. Jersey City, NJ. July 2023.
5. Hulio Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. August 2023.
6. Hyrimoz Prescribing Information. Sandoz Inc. Princeton, NJ. September 2023.
7. Idacio Prescribing Information. Fresenius Kabi. Lake Zurich, IL. October 2023.
8. Yuflyma Prescribing Information. Celltrion Inc. Jersey City, NJ. September 2023.
9. Yusimry Prescribing Information. Coherus BioSciences Inc. Redwood City, CA. September 2023.

5 . Revision History

Date	Notes
11/18/2023	Annual review - added Abrilada GPIs; background updates

Mavyret (glecaprevir/pibrentasvir)

Prior Authorization Guideline

Guideline ID	GL-126044
Guideline Name	Mavyret (glecaprevir/pibrentasvir)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	2/16/2017
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 06/16/2021 ; 11/18/2021 ; 06/15/2022 ; 6/21/2023

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

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1

AND

2 - Patient has experienced failure with a previous treatment regimen that included an NS5A inhibitor (e.g., Daklinza [daclatasvir])

AND

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)]

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 3; Treatment-Experienced (Interferon- or Sovaldi-based Regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 3

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included interferon, peginterferon, ribavirin, and/or Sovaldi (sofosbuvir)

AND

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])

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, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); without Cirrhosis
Approval Length	8 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

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])

AND

4 - Patient is without cirrhosis

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, 4, 5, or 6; Treatment-Experienced (Interferon-based Regimen); with Compensated Cirrhosis
Approval Length	12 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous interferon-based treatment regimen

AND

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])

AND

4 - Patient has compensated cirrhosis (e.g., Child-Pugh Class A)

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, 4, 5, or 6; Treatment-Experienced (Sovaldi-based regimen); without Decompensated Cirrhosis
Approval Length	16 Week(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5, or 6

AND

2 - Patient has experienced treatment failure with a previous treatment regimen that included Sovaldi (sofosbuvir)

AND

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])

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 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]:

- 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

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6

AND

2 - Patient has had a liver or kidney transplant [2]

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.

4 . Revision History

Date	Notes

6/6/2023	Annual review - removed HIV coinfection criteria since the guidelines no longer list HIV as a contraindication to the simplified treatment ap proach; background updates

Mekinist (trametinib)

Prior Authorization Guideline

Guideline ID	GL-134091
Guideline Name	Mekinist (trametinib)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 08/18/2022 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Mekinist (trametinib)
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. **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. **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. **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.

BRAF V600E mutation-positive unresectable or metastatic solid tumors Indicated, in combination with dabrafenib, for the treatment of adult and pediatric patients 1 year 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 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

Approval Criteria

1 - One of the following diagnoses: [2]

- 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 a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name: Mekinist	
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: Mekinist	
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 Tafinlar (dabrafenib)

Product Name: Mekinist	
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: Mekinist	
Diagnosis	Adjuvant 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 Tafinlar (dabrafenib)

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

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year 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 Tafinlar (dabrafenib)

Product Name: Mekinist	
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: Mekinist	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

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)

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. August 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.

5 . Revision History

Date	Notes
10/2/2023	update guideline

Mepsevii (vestronidase alfa-vjbk)

Prior Authorization Guideline

Guideline ID	GL-134227
Guideline Name	Mepsevii (vestronidase alfa-vjbk)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/15/2018
P&T Revision Date:	06/17/2020 ; 05/20/2021 ; 04/20/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Mepsevii (vestronidase alfa-vjbk)
Mucopolysaccharidosis (MPS VII, Sly Syndrome) Indicated for the treatment of Mucopolysaccharidosis (MPS VII, Sly Syndrome) in pediatric and adult patients. Limitations of use: The effect of Mepsevii on the central nervous system manifestations of MPS VII has not been determined.

2 . Criteria

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria **1** - Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)

Product Name: Mepsevii	
Diagnosis	Mucopolysaccharidosis (MPS VII, Sly Syndrome)
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. Mepsevii Prescribing Information. Ultragenyx Pharmaceutical Inc. Novato CA. December 2020.

4 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes t o clinical intent

Mitoxantrone

Prior Authorization Guideline

Guideline ID	GL-135827
Guideline Name	Mitoxantrone

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/18/2001
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Mitoxantrone
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. **Prostate Cancer** Indicated, in combination with corticosteroids, as initial chemotherapy for the treatment of patients with pain related to advanced hormone-refractory prostate cancer. **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.

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/mm^3

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Generic mitoxantrone	
Diagnosis	Multiple Sclerosis
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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/m^2 [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/mm^3

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

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/m^2 [1]

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

Approval Criteria

1 - Diagnosis of acute non-lymphocytic leukemia (ANLL) (e.g., myelogenous, promyelocytic, monocytic, and erythroid)

AND

2 - Used in combination with other medications used for the treatment of ANLL [9, 10]

AND

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)
Approval Length	6 Months [5-6, A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

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/m^2 [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

1. Mitoxantrone Prescribing Information. Fresenius Kabi USA, LLC. Lake Zurich, IL. December 2019.
2. Hartung HP, Gonsette R, Konig N, et al. Mitoxantrone in progressive multiple sclerosis: a placebo-controlled, double-blind, randomized, mulitcentre trial. Lancet 2002;360:2018-25.
3. Marriott JJ, Miyasaki JM, Gronseth G, O'Connor PW. Evidence Report: The efficacy and safety of mitoxantrone (Novantrone) in the treatment of multiple sclerosis: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2010;74:1463-70.
4. Avasarala JR, Cross AH, Clifford DB, Singer BA, Siegal BA, Abbey EE. Rapid onset mitoxantrone-induced cardiotoxicity in secondary progressive multiple sclerosis. Mult Scler. 2003;9:59-62.
5. Ghalie RG, Edan G, Laurent M, et al. Cardiac adverse effects associated with mitoxantrone (Novantrone) therapy in patients with MS. Neurology. 2002;59:909-13.
6. Bastianello S, Pozzilli C, D'Andrea F, et al. A controlled trial of mitoxantrone in multiple sclerosis: serial MRI evaluation at one year. Can J Neurol Sci. 1994;21:266-70.
7. Petrylak DP, Tangen CM, Hussain MH, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. N Engl J Med. 2004;351:1513-20.
8. Tannock IF, de Wit R, Berry WR, et al. Investigators. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med. 2004;351:1502-12.
9. Anderson JE, Kopecky KJ, Willman CL, et al. Outcome after induction chemotherapy for older patients with acute myeloid leukemia is not improved with mitoxantrone and etoposide compared to cytarabine and daunorubicin: a Southwest Oncology Group study. Blood. 2002;100:3869-76. Epub 2002 Aug 1.
10. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed May 3, 2023.
11. Rae-Grant, A., Day, G., Marrie, R., Rabinstein, A., Cree, B., Gronseth, G., Haboubi, M., Halper, J., Hosey, J., Jones, D., Lisak, R., Pelletier, D., Potrebic, S., Sitcov, C., Sommers, R., Stachowiak, J., Getchius, T., Merillat, S. and Pringsheim, T., 2018. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), pp.777-788.

5 . Revision History

Date	Notes
11/2/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Prior Authorization Guideline

Guideline ID	GL-135560
Guideline Name	Multiple Sclerosis (MS) Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/20/2000
P&T Revision Date:	08/19/2021 ; 12/15/2021 ; 12/15/2021 ; 05/19/2022 ; 12/14/2022 ; 12/14/2022 ; 12/14/2022 ; 4/5/2023

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: 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: Lemtrada (alemtuzumab)
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, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS. Limitations of Use: Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile.
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: Ocrevus (ocrelizumab)

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. **Primary Progressive Forms of Multiple Sclerosis (PPMS)** Indicated for the treatment of primary progressive MS, 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: Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Generic glatiramer acetate, Glatopa, Kesimpta*, Mayzent, Vumerity	
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

Notes	*For Kesimpta, there is a QL Override (For new starts only): Please e nter 2 PAs as follows with the same start date: First PA: Approve 3 syr inges or pens per 28 days for the first month (Loading dose has a MD D of 0.05); Second PA: Approve 1 syringe or pen per 28 days (no ove rrides 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. Ma intenance dose has a MDD of 0.02)

Product Name: Aubagio, Kesimpta, Vumerity	
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

Product Name: Extavia, Plegridy, 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:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Glatopa (glatiramer acetate)
- Kesimpta (ofatumumab)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Extavia, Plegridy, Ponvory, Rebif	
Approval Length	12 month(s)
Guideline Type	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 - One of the following:

2.1 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

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to at least two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Bafiertam (monomethyl fumarate)
- Glatopa (glatiramer acetate)
- Dimethyl fumarate

AND

3 - Prescribed by or in consultation with a neurologist

Product Name: Aubagio, Avonex, Bafiertam, Betaseron, Brand Copaxone, Extavia, Generic glatiramer acetate, Glatopa, Kesimpta, Mayzent, Plegridy, Ponvory, Rebif, Vumerity	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (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 alemtuzumab

AND

2.1.2 Failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Lemtrada	
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of a relapsing form of multiple sclerosis (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 alemtuzumab

AND

2.1.2 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to two of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

OR

2.2 Both of the following: [E]

2.2.1 Patient has previously received treatment with alemtuzumab

AND

2.2.2 At least 12 months have or will have elapsed since the most recent treatment course with alemtuzumab

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Prescribed by or in consultation with a neurologist

Product Name: Mavenclad	
Approval Length	1 month(s)
Guideline Type	Prior Authorization

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:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

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

Product Name: Mavenclad	
Approval Length	1 month(s)
Guideline Type	Non Formulary

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 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

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

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of 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 disease, secondary progressive disease, including active disease with new brain lesions) [A]

AND

2 - One of the following:

2.1 Failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Kesimpta (ofatumumab)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

OR

2.2 For continuation of prior therapy

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus

Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Relapsing Forms of MS
Approval Length	12 month(s)
Guideline Type	Non Formulary

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 - One of the following:

2.1 Paid claims or submission of medical records (e.g., chart notes) confirming failure after a trial of at least 4 weeks, contraindication, or intolerance to one of the following disease-modifying therapies for MS:

- Avonex (interferon beta-1a)
- Betaseron (interferon beta-1b)
- Tysabri (natalizumab)
- Any one of the glatiramer acetate injections (e.g., 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)

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

AND

3 - Not used in combination with another disease-modifying therapy for MS

AND

4 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

5 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

6 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Ocrevus	
Diagnosis	Primary Progressive Multiple Sclerosis (PPMS)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of Primary Progressive Multiple Sclerosis (PPMS)

AND

2 - Not used in combination with another disease-modifying therapy for MS

AND

3 - Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra, Kesimpta]) [16]

AND

4 - Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone)

AND

5 - 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. According to Prescribing Information, the recommended dosage of Lemtrada is 12 mg/day administered by intravenous infusion for 2 treatment courses (first treatment course: 12 mg/day on 5 consecutive days; second treatment course: 12 mg/day on 3 consecutive days administered 12 months after the first treatment course). Following the second treatment course, subsequent treatment courses of 12 mg per day on 3 consecutive days (36 mg total dose) may be administered, as needed, at least 12 months after the last dose of any prior treatment courses. [13]
F. 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. [19]

4 . References

1. Avonex Prescribing Information. Biogen Inc. Cambridge, MA. March 2020.
2. Betaseron Prescribing Information. Bayer. Whippany, NJ. October 2020.

3. Copaxone Prescribing Information. Teva Pharmaceuticals. North Wales, PA. July 2020.
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. Aubagio Prescribing Information. Genzyme Corporation. Cambridge, MA. November 2020.
11. Lemtrada Prescribing Information. Genzyme Corporation. Cambridge, MA. September 2020.
12. Glatopa Prescribing Information. Sandoz Inc. Princeton, NJ. January 2020.
13. Hawker K, O'Connor P, Freedman MS, et al. Rituximab in patients with primary progressive multiple sclerosis: results of a randomized double-blind placebo-controlled multicenter trial. Ann Neurol. 2009; Oct;66(4):460-71.
14. Ocrevus Prescribing Information. Genentech, Inc. San Francisco, CA. December 2020.
15. Mayzent Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. January 2021.
16. Mavenclad Prescribing Information. EMD Serono, Inc. Rockland, MA. April 2019.
17. Vumerity Prescribing Information. Biogen Inc. Cambridge, MA. January 2021.
18. Bafiertam Prescribing Information. Banner Life Sciences. High Point, NC. April 2020.
19. Kesimpta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. August 2020.
20. Hauser S, Bar-Or A, Cohen J et al. Ofatumumab versus Teriflunomide in Multiple Sclerosis. New England Journal of Medicine. 2020;383(6):546-557.
21. Ponvory Prescribing Information. Janssen Pharmaceuticals Inc. Titusville, NJ. March 2021.

5 . Revision History

Date	Notes
10/30/2023	target drugs that have "Copaxone/Glatopa (glatiramer acetate)" listed as a trial option, revised to say "Glatopa (glatiramer acetate).

Myalept (metreleptin for injection)

Prior Authorization Guideline

Guideline ID	GL-134528
Guideline Name	Myalept (metreleptin for injection)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/21/2014
P&T Revision Date:	08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 08/17/2023 ; 11/17/2023

Note:

Program update to standard reauthorization language. No changes to clinical intent.

1 . Indications

Drug Name: Myalept (metreleptin for injection)
Congenital or acquired generalized lipodystrophy Indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy

2 . 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: [2]

- 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 - Patient demonstrates positive clinical response to therapy, such as one of the following:

- Sustained reduction in hemoglobin A1c level from baseline

- Sustained reduction in triglyceride levels from baseline

3 . References

1. Myalept Prescribing Information. Amryt Pharmaceuticals DAC. Dublin, Ireland. March 2023.
2. Handelsman Y, Oral EA, Bloomgarden ZT, et al. The clinical approach to the detection of lipodystrophy – an AACE consensus statement. Endocrine Practice 2013;19(1):107-116.
3. Araujo-Vilar, D., Santini, F. Diagnosis and Treatment of Lipodystrophy: A Step-by-Step Approach. Journal of Endocrinological Investigation volume 42, pages61–73 (2019). Available at https://link.springer.com/article/10.1007/s40618-018-0887-z. Accessed July 13, 2022.

4 . Revision History

Date	Notes
10/10/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Naglazyme (galsulfase injection)

Prior Authorization Guideline

Guideline ID	GL-134228
Guideline Name	Naglazyme (galsulfase injection)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/1/2006
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 6/21/2023

1 . Indications

Drug Name: Naglazyme (galsulfase injection)
Mucopolysaccharidosis (MPS VI) Indicated for patients with Mucopolysaccharidosis VI (MPS VI). Naglazyme has been shown to improve walking and stair-climbing capacity.

2 . Criteria

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

Approval Criteria **1** - Diagnosis of Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy Syndrome)

Product Name: Naglazyme	
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. Naglazyme Prescribing Information. BioMarin Pharmaceuticals Inc. April 2020.

4 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes t o clinical intent

Nexavar (sorafenib)

Prior Authorization Guideline

Guideline ID	GL-127298
Guideline Name	Nexavar (sorafenib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/4/2006
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 07/20/2022 ; 06/21/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of advanced renal cell carcinoma

AND

2 - Trial and failure or intolerance to generic sorafenib (Applies to Brand Nexavar only)

Product Name: Brand Nexavar, generic sorafenib	
Diagnosis	Renal cell carcinoma
Approval Length	12 Months [B]
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	Hepatocellular carcinoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hepatocellular carcinoma

AND

2 - 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 - 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.

5 . Revision History

Date	Notes
6/29/2023	Removed specialist requirement

Ninlaro (ixazomib citrate)

Prior Authorization Guideline

Guideline ID	GL-127501
Guideline Name	Ninlaro (ixazomib citrate)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 06/15/2022 ; 03/15/2023 ; 06/21/2023 ; 7/19/2023

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	

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.

4 . Revision History

Date	Notes
7/3/2023	Removed specialist requirement

Nityr and Orfadin

Prior Authorization Guideline

Guideline ID	GL-134230
Guideline Name	Nityr and Orfadin

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/18/2018
P&T Revision Date:	11/14/2019 ; 06/17/2020 ; 03/17/2021 ; 07/21/2021 ; 08/18/2022 ; 08/17/2023 ; 8/17/2023

1 . Indications

Drug Name: Nityr (nitisinone) tablets
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.
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

Approval Criteria

1 - Diagnosis of hereditary tyrosinemia type 1 (HT-1)

AND

2 - Diagnosis confirmed by the presence of succinylacetone in the plasma or urine [1-3]

AND

3 - Used in combination with dietary restriction of tyrosine and phenylalanine

AND

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

- Gastroenterologist
- Hepatologist
- Other specialist with experience in treating inborn errors of metabolism

Notes	*For patients who have difficulties swallowing intact tablets, including pediatric patients, the tablets can be disintegrated in water and admini stered using an oral syringe. If patients can swallow semi-solid foods, the tablets can also be crushed and mixed with applesauce. For prepa ration and administration instructions, see the full prescribing informati on [1].

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
Approval Criteria **1** - Patient demonstrates a positive clinical response to therapy	
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.

3 . References

1. Nityr prescribing information. Cycle Pharmaceuticals Ltd. Cambridge, UK. June 2021.
2. Orfadin prescribing Information. Sobi Inc. Waltham, MA. November 2021.
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.

4 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes to clinical intent

Nplate (romiplostim)

Prior Authorization Guideline

Guideline ID	GL-135481
Guideline Name	Nplate (romiplostim)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/7/2009
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 04/21/2021 ; 02/17/2022 ; 02/16/2023 ; 2/16/2023

1 . Indications

Drug Name: Nplate (romiplostim)
Immune Thrombocytopenia (ITP) Indicated for the treatment of thrombocytopenia in adult patients with immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and in pediatric patients 1 year of age and older with ITP for at least 6 months who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Limitations of Use: - Nplate is not indicated for the treatment of thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP. - Nplate should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increases the risk for bleeding. - Nplate should not be used in an attempt to normalize platelet counts. **Hematopoietic Syndrome of Acute Radiation Syndrome** Indicated to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation.

2 . Criteria

Product Name: Nplate	
Diagnosis	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:

- Immune thrombocytopenia (ITP) [A]
- Relapsed/refractory ITP [4]

AND

2 - Baseline platelet count is less than 30,000/mcL [2-4]

AND

3 - Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [2]

- Corticosteroids (e.g., dexamethasone, prednisone)
- Immune globulins (e.g., Gammaplex, Gammagard S/D)
- Splenectomy

AND

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

Product Name: Nplate	
Diagnosis	Immune Thrombocytopenia (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name: Nplate	
Diagnosis	Hematopoietic Syndrome of Acute Radiation Syndrome
Approval Length	14 Day(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hematopoietic syndrome of acute radiation syndrome

AND

2 - Patient is acutely exposed to myelosuppressive doses of radiation

AND

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

3 . Endnotes

A. ITP has previously been called idiopathic thrombocytopenic purpura, immune thrombocytopenic purpura, or autoimmune thrombocytopenic purpura (AITP). These

terms have been replaced by "immune thrombocytopenia" to reflect the known autoantibody mechanism and the absence of purpura in some patients. [5]

4 . References

1. Nplate Prescribing Information. Amgen Inc. Thousand Oaks, CA. February 2022.
2. Kuter DJ, Bussel JB, Lyons RM, et al. Efficacy of romiplostim in patients with chronic immume thrombocytopenic purpura: a double-blind randomised controlled trial. Lancet. 2008; 371:395-403.
3. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Available at: https://ashpublications.org/bloodadvances/article/3/23/3829/429213/American-Society-of-Hematology-2019-guidelines-for. Accessed December 9, 2022.
4. Per clinical consult with hematologist/oncologist, June 20, 2018.
5. Immune thrombocytopenia (ITP) in adults: Clinical manifestations and diagnosis. UpToDate Website. Available at: www.uptodate.com. Accessed December 9, 2022.

5 . Revision History

Date	Notes
10/26/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Nucala (mepolizumab)

Prior Authorization Guideline

Guideline ID	GL-134232
Guideline Name	Nucala (mepolizumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/17/2015
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 02/13/2020 ; 12/16/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 07/20/2022 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

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 is 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 two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months [2-4, H]

OR

3.2 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 - Patient demonstrates 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	12 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 - Used in combination with another agent for CRSwNP [J]

AND

4 - 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 - Patient demonstrates 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 - Patient demonstrates 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-PDGFRA)-negative

AND

5 - Patient has uncontrolled HES defined as both of the following:

- History of 2 or more flares within the past 12 months [I]
- 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 - Patient demonstrates 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.

6 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes t o clinical intent

Prior Authorization Guideline

Guideline ID	GL-136531
Guideline Name	Octreotide Products - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/19/2001
P&T Revision Date:	11/14/2019 ; 07/15/2020 ; 09/16/2020 ; 12/16/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022 ; 12/13/2023

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. **Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing** Indicated for the treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors. Limitations of Use: Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects. **Vasoactive Intestinal Peptide Tumors (VIPomas), for Symptomatic Treatment of Diarrhea** Indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors. Limitations of Use: Improvement in clinical signs and symptoms, or reduction in tumor size or rate of growth, were not shown in clinical trials performed with Sandostatin Injection; these trials were not optimally designed to detect such effects.

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: 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	
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
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Trial and failure, contraindication, or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses

AND

4 - One of the following:

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 only)

Product Name: Mycapssa	
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
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

AND

3 - Patient has responded to and tolerated treatment with generic octreotide or lanreotide

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR, Mycapssa	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size)

Product Name: Brand Sandostatin, Generic octreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)

Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

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

Approval Criteria

1 - Diagnosis of acromegaly

AND

2 - One of the following:

2.1 Inadequate response to one of the following:

- Surgery
- Pituitary irradiation

OR

2.2 Not a candidate for surgical resection or pituitary irradiation

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	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes

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 only)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR	
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	
Diagnosis	Carcinoid Tumors, for Symptomatic Treatment of Diarrhea or Flushing
Approval Length	12 month(s)
Guideline Type	Non Formulary

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	
Diagnosis	Vasoactive Intestinal Peptide Tumors, for Symptomatic Treatment of Diarrhea
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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)

Product Name: Brand Sandostatin, Generic octreotide, Sandostatin LAR	
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, generic octreotide	
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. November 2023.
2. Sandostatin LAR Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2023.
3. Octreotide Prescribing Information. Mylan Institutional LLC. Morgantown, WV. November 2022.
4. Mycapssa Prescribing Information. MW Encap Ltd. Scotland, UK. September 2023.

4 . Revision History

Date	Notes
12/1/2023	Annual review: Removed Bynfezia pen as target, obsolete date 5/14/ 2023; updated indications in line with prescribing guidelines; updated references. Updated standard reauth criteria to say "Patient demons trates positive clinical response to therapy".

Odomzo (sonidegib)

Prior Authorization Guideline

Guideline ID	GL-132220
Guideline Name	Odomzo (sonidegib)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	10/13/2015
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

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	
Diagnosis	Basal Cell Carcinoma
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

Product Name: Odomzo	
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 . 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.

5 . Revision History

Date	Notes
9/1/2023	Annual Review - no criteria changes

Olumiant (baricitinib)

Prior Authorization Guideline

Guideline ID	GL-136963
Guideline Name	Olumiant (baricitinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/16/2018
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 12/18/2019 ; 04/15/2020 ; 09/16/2020 ; 04/21/2021 ; 07/21/2021 ; 10/20/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022 ; 04/19/2023 ; 07/19/2023 ; 12/13/2023

1 . Indications

Drug Name: Olumiant (baricitinib)
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. **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). **Alopecia Areata (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.

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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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	*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. **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	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 or cyclosporine)**

Notes	**Olumiant may be used with concomitant methotrexate, topical or inh aled corticosteroids, and/or low stable dosages of oral corticosteroids (equivalent to 10 mg or less of prednisone daily).

Product Name: Olumiant	
Diagnosis	Coronavirus disease 2019 (COVID-19)
Approval Length	14 Day(s)
Guideline Type	Prior Authorization, Non Formulary

Approval Criteria

1 - Diagnosis of COVID-19

AND

2 - Patient is hospitalized

AND

3 - Patient requires one of the following:

- 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

Approval Criteria

1 - Diagnosis of alopecia areata

AND

2 - Patient has at least 50% scalp hair loss [1, 4]

AND

3 - Other causes of hair loss have been ruled out (e.g., androgenetic alopecia, trichotillomania, other scalp disease) [4]

AND

4 - Prescribed by or in consultation with a dermatologist

AND

5 - Not used in combination with other Janus kinase (JAK) inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*	
Notes	*Olumiant may be used with concomitant methotrexate, topical or inha led 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
Approval Criteria **1** - Patient demonstrates positive clinical response to therapy **AND** **2** - Not used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or potent immunosuppressants (e.g., azathioprine)*	
Notes	*Olumiant may be used with concomitant methotrexate, topical or inha led 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.

4 . Revision History

Date	Notes
11/30/2023	Removed drug-specific non-formulary criteria; in alopecia criteria, up dated examples listed for "other causes of hair loss have been ruled out"; updated reauth verbiage to "patient demonstrates"

Oncology Injectable

Prior Authorization Guideline

Guideline ID	GL-135399
Guideline Name	Oncology Injectable

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/19/2018
P&T Revision Date:	02/13/2020 ; 03/18/2020 ; 08/13/2020 ; 03/17/2021 ; 10/20/2021 ; 11/18/2021 ; 03/16/2022 ; 09/21/2022 ; 10/19/2022 ; 01/18/2023 ; 03/15/2023 ; 05/18/2023 ; 06/21/2023 ; 07/19/2023 ; 08/17/2023 ; 09/20/2023 ; 10/18/2023 ; 11/16/2023

1 . Criteria

Product Name: Adcetris, Aliqopa, Arzerra, Blincyto, Cyramza, Elzonris, Erbitux, Firmagon, Folotyn, Brand Pralatrexate, Jemperli, Kadcyla, Keytruda, Lumoxiti, Margenza, Monjuvi, Opdivo, Padcev, Phesgo, Polivy, Portrazza, Poteligeo, Rylaze, Tecentriq, Tivdak, Yervoy, Zepzelca	
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

Product Name: Abecma, Breyanzi, Carvykti, Kymriah, Tecartus, Yescarta	
Approval Length	1 Time Authorization in Lifetime
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 All 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

AND

1.1.3 Patient has not previously received CAR-T Cell Therapy for the requested indication

OR

1.2 Meets the off-label administrative guideline criteria

2 . Revision History

Date	Notes
10/24/2023	Addition of Kadcyla and Tivdak to guideline

Onpattro (patisiran) & Tegsedi (inotersen)

Prior Authorization Guideline

Guideline ID	GL-122099
Guideline Name	Onpattro (patisiran) & Tegsedi (inotersen)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	10/17/2018
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Onpattro (patisiran), Tegsedi (inotersen)
Hereditary transthyretin-mediated amyloidosis Indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

2 . Criteria

Product Name: Onpattro or 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 ≤ IIIb
- Patient has a baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2
- Patient has a baseline neuropathy impairment score (NIS) between 5 and 130 for Onpattro or a baseline neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

AND

5 - Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy) [2, 4]

Product Name: Onpattro or 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 ≤ 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 5 and 130 for Onpattro or a neuropathy impairment score (NIS) between 10 and 130 for Tegsedi

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.

4 . Revision History

Date	Notes
3/6/2023	2023 Annual Review.

Onureg (azacitidine)

Prior Authorization Guideline

Guideline ID	GL-136506
Guideline Name	Onureg (azacitidine)

Guideline Note:

Effective Date:	2/1/2024
P&T Approval Date:	11/12/2020
P&T Revision Date:	11/18/2021 ; 11/17/2022 ; 07/19/2023 ; 12/13/2023

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

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. Summt, NJ. October 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia. v6.2023. Available by subscription at:

https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed October 20, 2023.

4 . Revision History

Date	Notes
12/1/2023	2023 Annual review. Updated references.

Orencia (abatacept)

Prior Authorization Guideline

Guideline ID	GL-137432
Guideline Name	Orencia (abatacept)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/28/2008
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 02/17/2022 ; 03/16/2022 ; 04/20/2022 ; 10/19/2022 ; 12/14/2022 ; 04/19/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Orencia (abatacept) IV and SC
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. **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. **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.
Drug Name: Orencia (abatacept) IV

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.

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

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 - 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 pegol)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Orencia IV or Orencia SC	
Diagnosis	Rheumatoid Arthritis (RA)
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

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

Approval Criteria

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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Xeljanz (tofacitinib)

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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Orencia IV or Orencia SC	
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

Product Name: Orencia IV or Orencia SC	
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 (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 - One of the following:

4.1 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)
- Skyrizi (risankizumab-rzaa)
- Tremfya (guselkumab)
- Rinvoq (upadacitinib)
- Xeljanz/XR (tofacitinib/ER)

OR

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

Product Name: Orencia IV or Orencia SC	
Diagnosis	Psoriatic Arthritis (PsA)
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, 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

Product Name: Orencia IV	
Diagnosis	Prophylaxis for Acute Graft versus Host Disease (aGVHD)
Approval Length	2 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Used for prophylaxis of acute graft versus host disease (aGVHD)

AND

2 - Patient is 2 years of age or older

AND

3 - Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor

AND

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

AND

5 - Used in combination with both of the following:

- 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.

4 . Revision History

Date	Notes
12/6/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Orgovyx (relugolix)

Prior Authorization Guideline

Guideline ID	GL-121699
Guideline Name	Orgovyx (relugolix)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	03/17/2021 ; 02/17/2022 ; 3/15/2023

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. September 2022.

4 . Revision History

Date	Notes
2/27/2023	2023 UM Annual Review. No changes to criteria. Updated references .

Orkambi (lumacaftor/ivacaftor)

Prior Authorization Guideline

Guideline ID	GL-124331
Guideline Name	Orkambi (lumacaftor/ivacaftor)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	6/10/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 10/19/2022 ; 4/19/2023

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. February 2023.

4 . Revision History

Date	Notes
4/6/2023	Annual review: No criteria changes. Updated references.

Orserdu (elacestrant)

Prior Authorization Guideline

Guideline ID	GL-127115
Guideline Name	Orserdu (elacestrant)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/19/2023
P&T Revision Date:	7/19/2023

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]

Product Name: Orserdu	
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 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.

5 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Otezla (apremilast)

Prior Authorization Guideline

Guideline ID	GL-137213
Guideline Name	Otezla (apremilast)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/21/2014
P&T Revision Date:	10/16/2019 ; 09/16/2020 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022 ; 10/18/2023 ; 10/18/2023

1 . Indications

Drug Name: Otezla (apremilast)
Psoriatic Arthritis (PsA) Indicated for the treatment of adult patients with active psoriatic arthritis. **Plaque Psoriasis (PsO)** 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	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 [2]:

- 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: Otezla	
Diagnosis	Psoriatic Arthritis (PsA)
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, 2]:

- 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: Otezla	
Diagnosis	Plaque psoriasis (PsO)
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 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

3 - Prescribed by or in consultation with a dermatologist

Product Name: Otezla	
Diagnosis	Plaque psoriasis (PsO)

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 ONE of the following [1, 4]:

- 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	6 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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy(e.g., reduction in pain from oral ulcers or reduction in number of oral ulcers)

3 . References

1. Otezla Prescribing Information. Amgen Inc. Thousand Oaks, CA. July 2023.
2. 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.
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. 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.

4 . Revision History

Date	Notes
11/30/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Perjeta (pertuzumab)

Prior Authorization Guideline

Guideline ID	GL-126677
Guideline Name	Perjeta (pertuzumab)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	8/21/2012
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Perjeta (pertuzumab)
Metastatic Breast Cancer (first-line therapy) Indicated in combination with trastuzumab and docetaxel for the treatment of patients with human epidermal growth factor receptor (HER2)-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease. **Neoadjuvant Treatment of Breast Cancer** Indicated for use in combination with trastuzumab and chemotherapy for the neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer. **Early Breast Cancer** Indicated for the use in combination with trastuzumab and chemotherapy as adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence **Off Label Uses: Metastatic Breast Cancer (second-line therapy)** May be considered in combination with trastuzumab with or without cytotoxic therapy (eg, vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab. [3]

2 . Criteria

Product Name: Perjeta	
Diagnosis	Metastatic breast cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of human epidermal growth factor receptor (HER2)-positive metastatic breast cancer

AND

2 - One of the following:

2.1 Both of the following: [2,A]

2.1.1 Patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease

AND

2.1.2 Used in combination with both of the following:

- Herceptin (trastuzumab)
- A taxane (e.g., docetaxel, paclitaxel)

OR

2.2 Both of the following:

2.2.1 Patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta

AND

2.2.2 Used in combination with Herceptin (trastuzumab)

Product Name: Perjeta	
Diagnosis	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

Product Name: Perjeta	
Diagnosis	Early Stage, Locally-Advanced, or Inflammatory Breast Cancer - Neoadjuvant
Approval Length	6 Month* [B]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses: [C]

- HER2-positive early stage breast cancer
- HER2-positive locally advanced breast cancer
- HER2-positive inflammatory breast cancer

AND

2 - Used in combination with both of the following: [C]

- Herceptin (trastuzumab)

• Chemotherapy	
Notes	*There is insufficient evidence to recommend continued use of Perjeta for greater than 6 cycles for early breast cancer. [1]

Product Name: Perjeta	
Diagnosis	Early Breast Cancer - At High Risk of Recurrence - Adjuvant Treatment
Approval Length	12 Month [D]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2- positive early breast cancer

AND

2 - Patient is at high risk of recurrence

AND

3 - Used in combination with both of the following:

- Herceptin (trastuzumab)
- Chemotherapy

3 . Endnotes

A. Perjeta is used for recurrent or metastatic human epidermal growth factor receptor 2-positive disease that is either hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory or with symptomatic visceral disease: (1) as preferred first-line therapy in combination with trastuzumab with docetaxel or paclitaxel; or (2) may be considered in combination with trastuzumab with or without cytotoxic therapy (eg, vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab. [3]

B. The safety of Perjeta administered for greater than 6 cycles for early breast cancer has not been established. Perjeta should be administered every 3 weeks for 3 to 6 cycles as part of one of the following treatment regimens for early breast cancer. [1,4]
C. A pertuzumab-containing regimen can be administered to patients with T2 or N1, HER2-positive, early stage breast cancer. Patients who have not received a neoadjuvant pertuzumab-containing regimen can receive adjuvant pertuzumab. [2]
D. Perjeta and trastuzumab were administered intravenously every 3 weeks starting on Day 1 of the first taxane-containing cycle, for a total of 52 weeks (up to 18 cycles) or until recurrence or unmanageable toxicities [1]

4 . References

1. Perjeta Prescribing Information. Genentech, Inc. San Francisco, CA. February 2021.
2. National Comprehensive Cancer Network. Clinical practice guidelines in oncology: breast cancer. v1.,2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed March 10, 2021.
3. National Comprehensive Cancer Network. NCCN Drugs & Biologics Compendium: Pertuzumab. 2020. Available at: http://www.nccn.org/professionals/drug_compendium/MatrixGenerator/Matrix.aspx?AID=383. Accessed March 10, 2021.
4. Baselga J, Cortes J, Kim SB, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med. 2012;366:109-19.

5 . Revision History

Date	Notes
6/14/2023	Removed Oncologist specialist requirement

Piqray (alpelisib)

Prior Authorization Guideline

Guideline ID	GL-126165
Guideline Name	Piqray (alpelisib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/17/2019
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

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)
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.

4 . Revision History

Date	Notes
6/7/2023	2023 Annual Review - removed prescriber requirement

Pomalyst (pomalidomide)

Prior Authorization Guideline

Guideline ID	GL-126544
Guideline Name	Pomalyst (pomalidomide)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	05/14/2020 ; 07/15/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Pomalyst (pomalidomide)
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. **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).

2 . Criteria

Product Name: Pomalyst	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

Product Name: Pomalyst	
Diagnosis	Kaposi Sarcoma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of AIDS-related Kaposi sarcoma

OR

1.2 Both of the following:

1.2.1 Diagnosis of Kaposi sarcoma

AND

1.2.2 Patient is HIV-negative

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.

4 . Revision History

Date	Notes
6/9/2023	Removed prescriber requirement.

Prolia (denosumab)

Prior Authorization Guideline

Guideline ID	GL-129188
Guideline Name	Prolia (denosumab)

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	8/17/2010
P&T Revision Date:	07/15/2020 ; 08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 8/17/2023

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

Approval Criteria

1 - Diagnosis of nonmetastatic prostate cancer

AND

2 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

2.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

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

Approval Criteria

1 - Patient is undergoing androgen deprivation therapy with one of the following: [11,A]

1.1 Luteinizing hormone-releasing hormone (LHRH)/gonadotropin releasing hormone (GnRH) agonist [e.g., Eligard/Lupron (leuprolide), Trelstar (triptorelin), Vantas (histrelin), and Zoladex (goserelin)]

OR

1.2 Bilateral orchiectomy (i.e., surgical castration)

AND

2 - No evidence of metastases

AND

3 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

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

Approval Criteria

1 - Patient is receiving adjuvant aromatase inhibitor therapy (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) [12]

AND

2 - Patient is benefiting from therapy (e.g., improved or stabilized BMD, no new fractures, improved biochemical markers, etc.)

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

Approval Criteria

1 - Diagnosis of postmenopausal osteoporosis or osteopenia [2,5]

AND

2 - One of the following: [5,17]

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	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

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	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 osteoperosis, 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 glucocorticod-induced osteoperosis at high risk for fractures. For patients in whom oral bisphosphonates are not appropriate, IV bisphosphonates should be considered. [18]

5 . References

1. Prolia prescribing information. Amgen Inc. Thousand Oaks, CA. January 2023.
2. Cummings SR, Martin JS, McClung MR, et al. Denosumab for prevention of fractures in postmenopausal women with osteoporosis. NEJM. 2009;361:756-765.
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. 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 July 9, 2021.
6. Qaseem A, Snow V, Shekelle P, et al. Pharmacologic treatment of low bone density or osteoporosis to prevent fractures: a clinical practice guideline from the American College of Physicians. Ann Intern Med. 2008;149:404-415.
7. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2010;16 Suppl 3:1-37.
8. Reid DM, Doughty J, Eastell R, et al. Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK Expert Group. Cancer Treat Rev. 2008;34 Suppl 1:S3-S18.
9. Body JJ, Bergmann P, Boonen S, et al. Management of cancer treatment-induced bone loss in early breast cancer and prostate cancer – a consensus paper of the Belgian Bone Club. Osteoporos Int. 2007;18:1439-1450.
10. Hillner BE, Ingle JN, Chlebowski RT, et al. American Society of Clinical Oncology 2003 update on the role of bisphosphonates and bone health issues in women with breast cancer. J Clin Oncol. 2003;21:4042-4057.
11. Smith MR, Egerdie B, Toriz NH, et al. Denosumab in men receiving androgen-deprivation therapy for prostate cancer. N Engl J Med. 2009;361:745-755.
12. Ellis GK, Bone HG, Chlebowski R, et al. Randomized trial of denosumab in patients receiving adjuvant aromatase inhibitors for nonmetastatic breast cancer. J Clin Oncol. 2008 Oct 20. 26:2875-4882.
13. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 20, 2020.
14. Saylor PJ, Kaufman DS, Michaelson MD, Lee RJ, Smith MR. Application of a fracture risk algorithm to men treated with androgen deprivation therapy for prostate cancer. J Urol. 2010;183:2200-2205.
15. Per clinical consult with oncologist. December 19, 2011.
16. 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.
17. Per clinical consultation with endocrinologist. January 30, 2018.
18. 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 July 2023.
19. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Prostate Cancer v.2.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 18, 2020.
20. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Breast Cancer v.4.2020. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed June 18, 2020.

6 . Revision History

Date	Notes
8/1/2023	Updated criteria for Glucocorticoid Induced Osteoporosis to align wit h 2022 update from ACR to include GC dosing of at least 30 mg or c umulative GC dose of at least 5 grams per year for high risk stratifica tion of patients. Updated references

Promacta (eltrombopag)

Prior Authorization Guideline

Guideline ID	GL-134266
Guideline Name	Promacta (eltrombopag)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/17/2009
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 02/18/2021 ; 02/17/2022 ; 2/17/2022

1 . Indications

Drug Name: Promacta (eltrombopag)
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. **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. **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.

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

Approval Criteria

1 - Diagnosis of one of the following:

- Persistent ITP
- Chronic ITP
- Relapsed/refractory ITP [8]

AND

2 - Baseline platelet count is less than 30,000/mcL [2, 3, 8]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [2, 3, 8]

- Corticosteroids
- Immunoglobulins
- Splenectomy

AND

4 - Patient’s degree of thrombocytopenia and clinical condition increase the risk of bleeding

AND

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

Product Name: Promacta	
Diagnosis	Persistent or Chronic Idiopathic Thrombocytopenic Purpura (ITP)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to Promacta therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding

Product Name: Promacta	
Diagnosis	First-Line for Severe Aplastic Anemia
Approval Length	6 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of severe aplastic anemia

AND

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]

AND

3 - Patient meets at least TWO of the following [9, 10]:

- 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
Approval Length	16 weeks [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

1 - Patient demonstrates positive clinical response to Promacta therapy as evidenced by an increase in platelet count

Product Name: Promacta	
Diagnosis	Chronic Hepatitis C-Associated Thrombocytopenia
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic hepatitis C-associated thrombocytopenia

AND

2 - One of the following:

2.1 Planning to initiate and maintain interferon-based treatment [1]

OR

2.2 Currently receiving interferon-based treatment

AND

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

Approval Criteria

1 - One of the following:

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:

1.1.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C [1]

AND

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]

OR

1.2 For patients that started treatment with Promacta while on concomitant treatment with interferon, Promacta will be approved based on the following criterion:

1.2.1 Currently on antiviral interferon therapy for treatment of chronic hepatitis C

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 x 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 x 10^9/L for Trial 1 and greater than or equal to 100 x 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.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Prior Authorization Guideline

Guideline ID	GL-135764
Guideline Name	Pulmonary Arterial Hypertension Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/15/2005
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 12/18/2019 ; 02/13/2020 ; 02/18/2021 ; 06/16/2021 ; 10/20/2021 ; 11/18/2021 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 07/19/2023 ; 06/21/2023

1 . Indications

Drug Name: Adcirca (tadalafil) Tablets, Alyq (tadalafil) Tablets, Tadliq (tadalafil) Oral Suspension
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%).
Drug Name: Adempas (riociguat) Tablets
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%).

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.

Drug Name: Flolan (epoprostenol sodium) Injection

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 tadalfil

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

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 - Patient is unable to take oral medications [2]

AND

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
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 - 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 Liqrev, 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

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Diagnosis of inoperable or persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH)

AND

1.1.2 CTEPH is symptomatic

OR

1.2 Patient is currently on any therapy for the diagnosis of CTEPH

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, Liqrev, 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, trail 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 Liqrev, 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

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

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: Uptravi 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. Uptravi 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.

5 . Revision History

Date	Notes
11/1/2023	Guideline cleanup. Removed duplicate criteria from Revatio oral sus pension guideline

Pulmozyme (dornase alfa inhalation solution)

Prior Authorization Guideline

Guideline ID	GL-135986
Guideline Name	Pulmozyme (dornase alfa inhalation solution)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/27/2015
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 4/19/2023

1 . Indications

Drug Name: Pulmozyme (dornase alpha) Inhalation Solution
Cystic Fibrosis Indicated, in conjunction with standard therapies, for the management of pediatric and adult patients with cystic fibrosis (CF) to improve pulmonary function. In CF patients with an FVC ≥ 40% of predicted, daily administration of PULMOZYME has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

2 . 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) [2,3]

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

Approval Criteria

1 - Diagnosis of cystic fibrosis (CF)

AND

2 - Patient demonstrates positive clinical response (i.e., improvement in lung function [forced expiratory volume in one second {FEV1}], decreased number of pulmonary exacerbations) to therapy

3 . References

1. Pulmozyme Prescribing Information. Genentech, Inc. South San Francisco, CA. July 2021.
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

4 . Revision History

Date	Notes

11/6/2023	Program update to standard reauthorization language. No changes t o clinical intent

Qinlock (ripretinib)

Prior Authorization Guideline

Guideline ID	GL-126179
Guideline Name	Qinlock (ripretinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/15/2020
P&T Revision Date:	07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Qinlock (ripretinib)
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.

4 . Revision History

Date	Notes
7/5/2023	Annual review - removed specialist requirement.

Reblozyl (luspatercept-aamt)

Prior Authorization Guideline

Guideline ID	GL-137690
Guideline Name	Reblozyl (luspatercept-aamt)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/1/2021
P&T Revision Date:	06/17/2020 ; 01/20/2021 ; 01/19/2022 ; 01/18/2023 ; 10/18/2023 ; 10/18/2023

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. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **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). Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia. **Myelodysplastic Syndromes Associated Anemia** Indicated for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red

blood cell (RBC) transfusions. Limitations of Use: Reblozyl is not indicated for use as a substitute for RBC transfusions in patients who require immediate correction of anemia.

2 . Criteria

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
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 beta thalassemia major [3]

AND

1.1.2 Patient requires regular red blood cell (RBC) transfusions

OR

1.2 Diagnosis of transfusion-dependent beta thalassemia [3]

AND

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

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Beta Thalassemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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

Approval Criteria

1 - One of the following diagnoses:

1.1 Very low-to intermediate-risk myelodysplastic syndrome with ring sideroblasts (MDS-RS)

OR

1.2 Myelodysplastic or myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)

AND

2 - Patient has failed an erythropoiesis stimulating agent [e.g., Epogen (epoetin alfa), Aranesp (darbepoetin)]

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

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

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of very low- to intermediate-risk myelodysplastic syndromes (MDS)

AND

2 - Patient does not have previous erythropoiesis stimulating agent use (ESA-naïve)

AND

3 - Patient requires transfusions of 2 or more red blood cell (RBC) units over 8 weeks

AND

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

- Hematologist
- Oncologist

Product Name: Reblozyl	
Diagnosis	Myelodysplastic Syndromes, Myelodysplastic/Myeloproliferative Neoplasm
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy (e.g., RBC transfusion independence, improvement in hemoglobin levels) [1,4]

3 . References

1. Reblozyl Prescribing Information. Celgene Corporation. Summit, NJ. August 2023.
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.

4 . Revision History

Date	Notes
12/12/2023	Updated reauth verbiage

Prior Authorization Guideline

Guideline ID	GL-129277
Guideline Name	Repository Corticotropin Gel Products - PA, NF

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	5/19/2009
P&T Revision Date:	08/15/2019 ; 08/15/2019 ; 08/13/2020 ; 08/19/2021 ; 02/17/2022 ; 08/18/2022 ; 8/17/2023

1 . Indications

Drug Name: Acthar Gel (repository corticotropin injection)
Infantile spasms [2, 3] Indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. **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. **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. **[Non-Approvable Use] 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.

[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).

[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 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.

[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

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: 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 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, 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 u se of Acthar or Purified Cortrophin Gel [A]

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.
6. Gillis T, Crane M, Hinkle C, et al. Repository corticotropin injection as adjunctive therapy in patients with rheumatoid arthritis who have failed previous therapies with at least three different modes of action. Open Access Rheumatol. 2017;9:131-138.
7. Brown, A. Repository corticotropin injection in patients with refractory psoriatic arthritis: a case series. Open Access Rheumatol. 2016;8:97-102.
8. Furie R, Mitrane M, Zhao E, et al. Efficacy and tolerability of repository corticotropin injection in patients with persistently active SLE: results of a phase 4, randomised, controlled pilot study. Lupus Sci Med. 2016;3(1):e000180.
9. Patel A, Seely G, Aggarwal R. Repository corticotropin injection for treatment of idiopathic inflammatory myopathies. Case Rep Rheumatol. 2016;2016:9068061.
10. Aggarwal R, Marder G, Koontz DC, et al. Efficacy and safety of adrenocorticotropic hormone gel in refractory dermatomyositis and polymyositis. Ann Rheum Dis. 2018 May;77(5):720-727.
11. Baughman RP, Sweiss N, Keijsers R, et al. Repository corticotropin for chronic pulmonary sarcoidosis. Lung. 2017;195(3):313-322.
12. Bomback AS, Tumlin JA, Baranski J, et al. Treatment of nephrotic syndrome with adrenocorticotropic hormone (ACTH) gel. Drug Des Devel Ther. 2011;5:147-153.
13. Bomback AS, Canetta PA, Beck Jr LH, et al. Treatment of resistant glomerular diseases with adrenocorticotropic hormone gel: A prospective trial. Am J Nephrol 2012;36:58-67.
14. Sharon Y, Chu DS. Adrenocorticotropic hormone gel for patients with non-infectious uveitis. Am J Ophthalmol Case Rep. 2019;15:100502.
15. Madan A, Mojovic-Das S, Stankovic A, et al. Acthar gel in the treatment of nephrotic syndrome: a multicenter retrospective case series. BMC Nephrol. 2016;17:37.
16. Purified Cortrophin Gel prescribing information. ANI Pharmaceuticals, Inc. Baudette, MN. June 2023.

5 . Revision History

Date	Notes
8/2/2023	Annual review: No criteria changes. Updated references and backgro und.

Retevmo (selpercatinib)

Prior Authorization Guideline

Guideline ID	GL-129271
Guideline Name	Retevmo (selpercatinib)

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	7/15/2020
P&T Revision Date:	08/19/2021 ; 08/18/2022 ; 12/14/2022 ; 07/19/2023 ; 8/17/2023

1 . Indications

Drug Name: Retevmo (selpercatinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test. **Medullary Thyroid Cancer (MTC)** Indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, 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). 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). **Thyroid Cancer** Indicated indicated for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, 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). 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).

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 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

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 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)

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

Product Name: Retevmo	
Diagnosis	Thyroid Cancer

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

Approval Criteria

1 - Diagnosis of thyroid cancer

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 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)

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: Retevmo	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Disease is ONE of the following:

- Locally Advanced
- Metastatic

AND

3 - Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s) [A, 1]

AND

4 - ONE of the following:

- Disease has progressed on or following prior systemic treatment (e.g., chemotherapy)
- There are no satisfactory alternative treatment options

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

Approval Criteria

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

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.

5 . Revision History

Date	Notes
8/2/2023	Annual review: No criteria changes. Updated indications.

Revcovi (elapegademase-lvlr)

Prior Authorization Guideline

Guideline ID	GL-120496
Guideline Name	Revcovi (elapegademase-lvlr)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	1/16/2019
P&T Revision Date:	01/15/2020 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Revcovi (elapegademase-lvlr)
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: Revcovi	
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.

4 . Revision History

Date	Notes
1/25/2023	Update program

Revlimid (lenalidomide)

Prior Authorization Guideline

Guideline ID	GL-126881
Guideline Name	Revlimid (lenalidomide)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/6/2006
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 04/20/2022 ; 04/19/2023 ; 05/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Revlimid (lenalidomide)
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] **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] **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] **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]

Marginal Zone Lymphoma (MZL) Revlimid in combination with a rituximab product, is 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	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of ONE of the following:

1.1 Smptomatic or transfusion-dependent anemia due to myelodysplastic syndrome (MDS) associated with a deletion 5q abnormality [2]

OR

1.2 Multiple Myeloma

OR

1.3 Relapsed or progressed mantle cell lymphoma (MCL)

OR

1.4 Follicular lymphoma (FL) that has been previously treated

OR **1.5** Marginal zone lymphoma (MZL) that has been previously treated

Product Name: Brand Revlimid, Generic lenalidomide	
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. 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.

5 . Revision History

Date	Notes

6/20/2023	Removal of specialist requirement

Prior Authorization Guideline

Guideline ID	GL-126212
Guideline Name	Riluzole Products - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	8/2/2005
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 10/20/2021 ; 07/20/2022 ; 7/19/2023

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.

4 . Revision History

Date	Notes
6/7/2023	2023 Annual Review - no changes

Rinvoq (upadacitinib)

Prior Authorization Guideline

Guideline ID	GL-134274
Guideline Name	Rinvoq (upadacitinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/16/2019
P&T Revision Date:	09/16/2020 ; 08/19/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 08/18/2022 ; 10/19/2022 ; 12/14/2022 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Rinvoq (upadacitinib)
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. **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. **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.

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.

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.

Crohn's Disease (CD) Indicated for the treatment of adult patients with moderately to severely active Crohn's disease 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 Crohn's disease, or with potent immunosuppressants such as azathioprine and cyclosporine.

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

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 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	Rheumatoid Arthritis (RA)
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 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	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]:

- 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 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	Psoriatic Arthritis (PsA)
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, 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).

Product Name: Rinvoq	
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 [5]

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 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	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 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., certolizumab pegol)

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).

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 - Patient demonstrates 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	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 [6, 7]:

- 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 (CDAI) greater than 220

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
- Azathioprine
- Corticosteroids (e.g., prednisone)
- Methotrexate

AND

5 - Patient has had an inadequate response or intolerance to one or more TNF inhibitors (e.g., adalimumab, certolizumab pegol)

AND

6 - Not used in combination with other JAK inhibitors, biological therapies for CD, 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).

Product Name: Rinvoq	
Diagnosis	Crohn's disease (CD)
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, 6, 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 other JAK inhibitors, biological therapies for CD, 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).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
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 - One of the following [8, 9]:

- 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 [8, 9]:

- 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., adalimumab, golimumab)

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).

Product Name: Rinvoq	
Diagnosis	Ulcerative Colitis (UC)
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, 8, 9]:

- 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 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).

Product Name: Rinvoq	
Diagnosis	Atopic Dermatitis (AD)
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 - Patient is 12 years of age or older

AND

3 - 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

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

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by at least ONE of the following:

- 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	*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 [10]

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

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. [11, 12] 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. [13]

5 . References

1. Rinvoq Prescribing Information. AbbVie Biotechnology Ltd. North Chicago, IL. May 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. 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. 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.
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.
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.

10. 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.
11. 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.
12. 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.
13. 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.

6 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Rituxan Hycela (rituximab and hyaluronidase human)

Prior Authorization Guideline

Guideline ID	GL-126257
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/26/2017
P&T Revision Date:	03/18/2020 ; 04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
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. **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. **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.

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

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

2 - One of the following:

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following

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

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

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

4 - One of the following:

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

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

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]

4 . References

1. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
2. Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 27, 2020.
5. Salles G, Seymour JF, Lopez-Guillermo A, et al. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomized controlled trial. Lancet. 2011;377(9759):42-51.

5 . Revision History

Date	Notes
6/5/2023	Removed prescriber requirement.

Prior Authorization Guideline

Guideline ID	GL-126258
Guideline Name	Rituxan Hycela (rituximab and hyaluronidase human) - UM Optimization

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/26/2017
P&T Revision Date:	06/15/2022 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Rituxan Hycela (rituximab and hyaluronidase human)
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. **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. **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.

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

Approval Criteria

1 - Diagnosis of follicular lymphoma

AND

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

2.1 Disease is relapsed or refractory

OR

2.2 Patient exhibited complete or partial response to prior treatment with rituximab in combination with chemotherapy

OR

2.3 Disease is non-progressing or stable following prior treatment with first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy

OR

2.4 Both of the following:

2.4.1 Disease is previously untreated

AND

2.4.2 Medication is used in combination with first-line chemotherapy

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 Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

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 - Paid claims or submission of medical records (e.g., chart notes) confirming 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

Approval Criteria

1 - Diagnosis of diffuse large B-cell lymphoma

AND

2 - Disease is previously untreated

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy

AND

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

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

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 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is being used in combination with fludarabine and cyclophosphamide (FC) therapy

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 Ruxience

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing treatment regimen

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]

4 . References

1. Rixtuan Hycela Prescribing Information. Genentech, Inc. South San Francisco, CA. June 2021.
2. Habermann TM, Weller EA, Morrison VA, et al. Rituximab-CHOP versus CHOP alone or with maintenance rituximab in older patients with diffuse large B-cell lymphoma. J Clin Oncol. 2006;24(19):3121-3127.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed March 10, 2023.
4. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 27, 2020.
5. Salles G, Seymour JF, Lopez-Guillermo A, et al. Rituximab maintenance for 2 years in patients with high tumour burden follicular lymphoma responding to rituximab plus chemotherapy (PRIMA): a phase 3, randomized controlled trial. Lancet. 2011;377(9759):42-51.

5 . Revision History

Date	Notes
6/5/2023	Removed prescriber requirement.

Prior Authorization Guideline

Guideline ID	GL-136450
Guideline Name	Rituximab - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/18/2019
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 10/16/2019 ; 01/15/2020 ; 01/15/2020 ; 02/13/2020 ; 03/18/2020 ; 09/16/2020 ; 02/18/2021 ; 07/21/2021 ; 10/20/2021 ; 12/15/2021 ; 01/19/2022 ; 02/17/2022 ; 07/20/2022 ; 10/19/2022 ; 02/16/2023 ; 07/19/2023 ; 7/19/2023

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, Truxima, 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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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 Ruxience

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Ruxience	
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 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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Rituxan, Ruxience, Truxima, Riabni	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 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 [10, 26, 27]:

- Reduction in the total active (swollen and tender) joint count from baseline

- Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

AND

2 - At least 16 weeks have elapsed since last course of therapy [B]

Product Name: Riabni, Truxima	
Diagnosis	Rheumatoid Arthritis (RA)
Approval Length	1 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of moderately- to severely-active rheumatoid arthritis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming a 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 - Paid claims or submission of medical records (e.g., chart notes) confirming that medication is used in combination with methotrexate [A]

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)
- Enbrel (etanercept)
- Humira (adalimumab), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- Simponi (golimumab)
- Rinvoq (upadacitinib)
- Xeljanz (tofacitinib) or 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 BOTH of the following:

- Actemra (tocilizumab)
- Orencia (abatacept)

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 rituximab 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 at least one of the following [10, 26, 27]:

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

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Ruxience

Notes	*Includes attestation that a total of two TNF inhibitors have already be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Ruxience	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- 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

OR

1.2 Both of the following:

- 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, Truxima	
Diagnosis	Non-Hodgkin’s Lymphoma
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- 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

OR

1.2 Both of the following:

- 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 for Riabni, Truxima) [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 Ruxience

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Riabni, Truxima	
Diagnosis	Non-Hodgkin's Lymphoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following:

1.1 Both of the following: [10]

- 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

OR

1.2 Both of the following:

- 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

AND

2 - One of the following:

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

OR

2.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name: Ruxience	
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, 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

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 prescribed treatment regimen

Product Name: Riabni, Truxima	
Diagnosis	Chronic Lymphocytic Leukemia
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia [2, 12, 15-19]

AND

2 - Used in combination with fludarabine and cyclophosphamide

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 Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

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 x 10^9 / L [11]

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe Pemphigus Vulgaris

Product Name: Rituxan	
Diagnosis	Pemphigus Vulgaris
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Rituxan	
Diagnosis	Waldenstrom’s macroglobulinemia
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of relapsed/refractory Waldenstrom’s macroglobulinemia (off-label) [1, 2, 5-8]

Product Name: Ruxience

Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

Product Name: Riabni, Rituxan, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Used in combination with glucocorticoids (e.g., prednisone)

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 prescribed treatment regimen

Product Name: Riabni, Truxima	
Diagnosis	Wegener's Granulomatosis and Microscopic Polyangiitis
Approval Length	3 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - One of the following diagnoses:

- Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis)
- Microscopic Polyangiitis

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming medication is used in combination with glucocorticoids (e.g., prednisone)

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 Ruxience

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation

of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

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]

4 . References

1. DRUGDEX Information System [Internet database]. Greenwood Village, Colorado: Thomson Micromedex. Accessed January 27, 2022.
2. AHFS Drug Information (Adult and Pediatric) [Internet database]. Hudson, Ohio: Lexicomp. Accessed on January 27, 2022.
3. Stasi R, Pagano A, Stipa E, et al. Rituximab chimeric anti-CD20 monoclonal antibody treatment for adults with chronic idiopathic thrombocytopenic purpura. Blood. 2001;98:952-7.
4. Saleh MN, Moore M, Feinberg B, et al. A pilot study of anti-CD20 MoAB rituximab in patients with refractory immune thrombocytopenic purpura (ITP). Blood. 2001;96:521a.
5. Dimopoulos MA, Kiamouris C, Karkantaris C, et al. Prospective evaluation of rituximab for the treatment of waldenstrom's macroglobulinemia. Blood. 2000;96:169a.
6. Treon SP, Agus DB, Link B, et al. Rituximab is an active agent in waldenstrom's macroglobulinemia (WM).Proc Am Soc Clin Oncol. 2000;19:6a.
7. Weide R, Heymanns J, & Koppler H. The polyneuropathy associated with Waldenstrom's macroglobulinaemia can be treated effectively with chemotherapy and the anti-CD20 monoclonal antibody rituximab. Br J Haematol. 2000;109:838-841.
8. Byrd JC, White CA, Link B, et al. Rituximab therapy in Waldenstrom's macroglobulinemia: preliminary evidence of clinical activity. Ann Oncol. 1999;10:1525-7.
9. American College of Rheumatology 2008 Recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. Arthritis Rheum. 2008;59(6):762-784.

10. Rituxan Prescribing Information. Genentech, Inc. South San Francisco, CA. December 2021.
11. Gudbrandsdottir S, Birgens HS, Frederiksen H, et al. Rituximab and dexamethasone vs dexamethasone monotherapy in newly diagnosed patients with primary immune thrombocytopenia. Blood. 2013;121(11):1976-81.
12. George JN, Woolf SH, Raskob GE, et al. Idiopathic thrombocytopenic purpura: a practice guideline developed by explicit methods for the American Society of Hematology. Blood. 1996;88:3-40.
13. Stone JH, Merkel PA, Spiera R, et al. Rituximab versus cyclophosphamide for ANCA-associated vasculitis. N Engl J Med. 2010;363:221-32.
14. Per clinical consult with rheumatologist. March 10, 2014.
15. Byrd JC, Murphy T, Howard RS, et al. Rituximab using a thrice weekly dosing schedule in B-cell chronic lymphocytic leukemia and small lymphocytic lymphoma demonstrates clinical activity and acceptable toxicity. J Clin Oncol. 2001;19:2153-2164.
16. Byrd JC, Peterson BL, Morrison VA, et al. Randomized phase II study of fludarabine with concurrent versus sequential treatment with rituximab in symptomatic, untreated patients with B-cell chronic lymphocytic leukemia: results from Cancer and Leukemia Group B 9712 (CALGB 9712). Blood. 2003;101:6-14.
17. Schulz H, Klein SK, Rehwald U, et al. Phase 2 study of a combined immunochemotherapy using rituxumab and fludarabine in patients with chronic lymphocytic leukemia. Blood. 2002;100:3115-3120.
18. Keating MJ, O'Brien S, Albitar M, et al. Early results of a chemoimmunotherapy regimen of fludarabine, cyclophosphamide, and rituxumab as initial therapy for chronic lymphocytic leukemia. J Clin Oncol. 2005;23:4079-4088.
19. National Comprehensive Cancer Network. Practice Guidelines in Oncology - v. 2.2022. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed January 27, 2022.
20. Truxima Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. November 2022.
21. Ruxience Prescribing Information. Pfizer Ireland Pharmaceuticals USA, Inc. Cork, Ireland. November 2021.
22. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed February 27, 2020.
23. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. B-Cell Lymphomas. v.5.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed January 27, 2022.
24. Riabni Prescribing Information. Amgen, Inc. Thousand Oaks, CA. June 2022.
25. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Pediatric Aggressive Mature B-Cell Lymphomas. v.2.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf. Accessed February 2, 2022.
26. 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.
27. 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 . Revision History

Date	Notes
11/16/2023	Program update to standard reauthorization language. No changes t o clinical intent

Romidepsin Products

Prior Authorization Guideline

Guideline ID	GL-127458
Guideline Name	Romidepsin Products

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	5/18/2010
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 04/21/2021 ; 09/15/2021 ; 04/20/2022 ; 04/15/2023 ; 7/19/2023

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]

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, Folotyn (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.1.2023. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed March 8, 2023.
4. Romidepsin prescribing information. Teva Pharmaceuticals USA, Inc. North Wales, PA. December 2021.

5 . Revision History

Date	Notes
7/3/2023	Removed specialist requirement

Rozlytrek (entrectinib)

Prior Authorization Guideline

Guideline ID	GL-131824
Guideline Name	Rozlytrek (entrectinib)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

1 . Indications

Drug Name: Rozlytrek (entrectinib)
Non-small cell lung cancer (NSCLC) Indicated for the treatment of adult patients with ROS1-positive metastatic non-small cell lung cancer (NSCLC), as detected by an FDA-approved test. **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, as detected by an FDA-approved test 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. 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 the confirmatory trials.

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)

Product Name: Rozlytrek	
Diagnosis	Solid Tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

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. June 2023.

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.

5 . Revision History

Date	Notes
8/28/2023	2023 Annual Review

Rubraca (rucaparib)

Prior Authorization Guideline

Guideline ID	GL-127712
Guideline Name	Rubraca (rucaparib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/16/2017
P&T Revision Date:	08/18/2022 ; 03/15/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Rubraca (rucaparib)
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. **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.

2 . Criteria

Product Name: Rubraca

Diagnosis	Ovarian 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

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)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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	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. 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.

4 . Revision History

Date	Notes
7/6/2023	Annual Review - Removal of specialist requirement.

Rydapt (midostaurin)

Prior Authorization Guideline

Guideline ID	GL-126887
Guideline Name	Rydapt (midostaurin)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/28/2017
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 03/15/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of newly diagnosed acute myeloid leukemia (AML)

AND

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]

AND

3 - Used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation

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)

Product Name: Rydapt	
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. 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. November 2021.
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 February 27, 2023.
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 (muts): 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 February 27, 2023.

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/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools. Accessed December13, 2019.

5 . Revision History

Date	Notes
7/18/2023	Removed Oncology specialist requirement

Sabril (vigabatrin), Vigadrone

Prior Authorization Guideline

Guideline ID	GL-121789
Guideline Name	Sabril (vigabatrin), Vigadrone

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	11/14/2019 ; 03/18/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

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

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of infantile spasms [A]

AND

1.1.2 Patient is 1 month to 2 years of age

AND

1.1.3 One of the following:

1.1.3.1 Trial and failure or intolerance to generic vigabatrin tablets or oral suspension

OR

1.1.3.2 For continuation of prior therapy if the patient is established on brand Sabril

OR

1.2 All of the following: [A]

1.2.1 Diagnosis of complex partial seizures

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 vission 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 Laboritories, 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/rems/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.

5 . Revision History

Date	Notes
3/1/2023	Annual Review - No criteria changes

Sapropterin Products

Prior Authorization Guideline

Guideline ID	GL-133766
Guideline Name	Sapropterin Products

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	10/21/2020 ; 03/17/2021 ; 10/20/2021 ; 10/19/2022 ; 11/17/2022 ; 10/18/2023

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

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, Brand Javygtor	
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]

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 saproterin 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.

5 . Revision History

Date	Notes
10/2/2023	Annual Review

Signifor, Signifor LAR (pasireotide) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-134412
Guideline Name	Signifor, Signifor LAR (pasireotide) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 01/19/2022 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: Signifor LAR (pasireotide)
Acromegaly Indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option. **Cushing's disease** Indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.
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 LAR	
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:

- Inadequate response to surgery
- Patient is not a candidate for surgery

Product Name: Signifor LAR	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., patient's growth hormone level or insulin-like growth factor 1 level for age and gender has normalized/improved)

Product Name: Signifor, Signifor LAR	
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, Signifor LAR	
Diagnosis	Cushing's disease
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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)

Product Name: Signifor

Diagnosis	Cushing's disease
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

3 . Background

Benefit/Coverage/Program Information
Quantity Limit These products are 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.

4 . References

1. Signifor LAR Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ. July 2020.
2. Signifor Prescribing Information. Recordati Rare Diseases Inc. Lebanon, NJ . March 2020.

5 . Revision History

Date	Notes
11/20/2023	2023 annual review: Updated standard reauth criteria from "documen tation of..." to "Patient demonstrates positive clinical response to ther apy" with no change to clinical intent. Background updates.

Simponi, Simponi Aria (golimumab)

Prior Authorization Guideline

Guideline ID	GL-135573
Guideline Name	Simponi, Simponi Aria (golimumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	6/3/2009
P&T Revision Date:	11/14/2019 ; 12/16/2020 ; 11/18/2021 ; 10/19/2022 ; 11/16/2023

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

Approval Criteria

1 - Diagnosis of moderately to severely active RA

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 [3, 4]:

- methotrexate
- leflunomide
- sulfasalazine

AND

3 - Used in combination with methotrexate

AND

4 - Prescribed by or in consultation with a rheumatologist

Product Name: Simponi or Simponi Aria	
Diagnosis	Rheumatoid Arthritis (RA)
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

Product Name: Simponi Aria	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [2, 5]:

- 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

Approval Criteria

1 - Diagnosis of active PsA

AND

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 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 2, 6]:

- 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 - Patient demonstrates 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

Approval Criteria

1 - Diagnosis of moderately to severely active ulcerative colitis

AND

2 - One of the following [8, 9]:

- 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 - One of the following:

3.1 Patient is corticosteroid dependent (i.e., an inability to successfully taper corticosteroids without a return of the symptoms of UC)

OR

3.2 Trial and failure, contraindication, or intolerance to one of the following conventional therapies [1, 8, 9]

- 6-mercaptopurine
- Aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine)
- Azathioprine
- Corticosteroids (e.g., prednisone)

AND

4 - Prescribed by or in consultation with a gastroenterologist

Product Name: Simponi	
Diagnosis	Ulcerative Colitis (UC)
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, 8, 9]:

- 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.

4 . Revision History

Date	Notes
10/30/2023	Annual review - Updated standard reauth criteria verbiage to "Patient demonstrates..."

Skyclarys (omaveloxolone)

Prior Authorization Guideline

Guideline ID	GL-134278
Guideline Name	Skyclarys (omaveloxolone)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/18/2023
P&T Revision Date:	

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 - Patient demonstrates 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.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Skyrizi (risankizumab-rzaa)

Prior Authorization Guideline

Guideline ID	GL-125053
Guideline Name	Skyrizi (risankizumab-rzaa)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	08/15/2019 ; 06/17/2020 ; 09/16/2020 ; 05/20/2021 ; 07/21/2021 ; 03/16/2022 ; 05/19/2022 ; 08/18/2022 ; 10/19/2022 ; 02/16/2023 ; 5/18/2023

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

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

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

Approval Criteria

1 - Documentation of positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- 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

Approval Criteria

1 - Diagnosis of active psoriatic arthritis (PsA)

AND

2 - One of the following [4]:

- 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-14

Product Name: Skyrizi SC 150 mg	
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

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

Approval Criteria

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

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 (CDAI) 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]: • 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.

4 . Revision History

Date	Notes
5/3/2023	Annual review - removed 75 mg strength since it has been discontinued; background updates

Soliris (eculizumab)

Prior Authorization Guideline

Guideline ID	GL-118741
Guideline Name	Soliris (eculizumab)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/19/2014
P&T Revision Date:	09/18/2019 ; 12/18/2019 ; 02/13/2020 ; 01/20/2021 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 2/16/2023

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

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 600 mg weekly for the first 4 weeks

OR

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

AND

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

Product Name: Soliris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)

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

AND

2 - Prescribed medication is used for maintenance therapy and will not exceed 900 mg every 2 weeks

Product Name: Soliris	
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)

AND

2 - Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab)

AND

3 - One of the following:

3.1 For patients 18 years of age and older:

3.1.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

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

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

Product Name: Soliris	
Diagnosis	Neuromyelitis Optica Spectrum Disorder (NMOSD)
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 - One of the following:

3.1 Prescribed medication is used for induction therapy and will not exceed 900 mg weekly for the first 4 weeks

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 dose	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.

5 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes.

Somatuline Depot (lanreotide) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-132912
Guideline Name	Somatuline Depot (lanreotide) - PA, NF

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	11/13/2007
P&T Revision Date:	11/14/2019 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 07/20/2022 ; 10/19/2022 ; 10/18/2023

1 . Indications

Drug Name: Somatuline Depot (lanreotide)
Acromegaly Indicated for the long-term treatment of 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 growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal. **Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs)** Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival. **Carcinoid Syndrome** Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.
Drug Name: Lanreotide Injection
Acromegaly Indicated for the long-term treatment of 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 growth hormone (GH) and insulin growth factor-1 (IGF-1) levels to normal.

Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) Indicated for the treatment of adult patients with unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival.

Off Label Uses: Carcinoid Syndrome [3] Indicated for the treatment of adults with carcinoid syndrome; when used, it reduces the frequency of short-acting somatostatin analog rescue therapy.

2 . Criteria

Product Name: Somatuline Depot, Brand Lanreotide	
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

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot, Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to therapy, such as a reduction or normalization of IGF-1/GH level for same age and sex

Product Name: Brand Lanreotide	
Diagnosis	Acromegaly
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an endocrinologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 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 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 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 therapy

Product Name: Brand Lanreotide 120mg/0.5ml	
Diagnosis	Advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NET)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastroenteropancreatic neuroendocrine tumor (GEP-NET)

AND

2 - Disease is one of the following:

- Unresectable, locally advanced
- Metastatic

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
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

AND

3 - Trial and failure or intolerance to Somatuline Depot (Applies to Brand Lanreotide only)

AND

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

- Endocrinologist
- Oncologist

Product Name: Somatuline Depot 120mg/0.5mL, Brand Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
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 Lanreotide 120mg/0.5ml [off-label]	
Diagnosis	Carcinoid Syndrome
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of carcinoid syndrome

AND

2 - Used to reduce the frequency of short-acting somatostatin analog rescue therapy

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to Somatuline Depot

AND

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

- Endocrinologist
- Oncologist

3 . References

1. Somatuline Depot Prescribing Information. Ipsen Biopharmaceuticals, Inc. Cambridge, MA. February 2023.
2. Lanreotide Injection Prescribing Information. Cipla USA Inc. Warren, NJ. December 2021.
3. Lanreotide Acetate. In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/. Accessed September 12, 2023.

4 . Revision History

Date	Notes
10/19/2023	Annual review: no criteria changes.

Somavert (pegvisomant)

Prior Authorization Guideline

Guideline ID	GL-135410
Guideline Name	Somavert (pegvisomant)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/14/2006
P&T Revision Date:	12/18/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

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 - One of the following: [2]

3.1 Inadequate response, contraindication, or intolerance to a somatostatin analog (e.g., octreotide, Somatuline [lanreotide])

OR

3.2 Clinical rationale provided for preferred treatment with pegvisomant (e.g., comorbid diabetes mellitus is present with acromegaly)

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** - Patient demonstrates 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 Jr, Melmed S, Molitch ME, Murad MH, Utz A, Wass JA. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-51.

4 . Revision History

Date	Notes
11/20/2023	2023 annual review: Updated step through generic octreotide.

Sovaldi (sofosbuvir)

Prior Authorization Guideline

Guideline ID	GL-125987
Guideline Name	Sovaldi (sofosbuvir)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	2/18/2014
P&T Revision Date:	11/14/2019 ; 05/14/2020 ; 01/20/2021 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Sovaldi (sofosbuvir)
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. 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

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

Approval Criteria

1 - Diagnosis of chronic hepatitis C genotype 2 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 3 - Sovaldi Plus Ribavirin
Approval Length	24 Week(s)
Guideline Type	Prior Authorization

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

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 Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

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)

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) [2]

AND

3 - Used in combination with Mavyret (glecaprevir/pibrentasvir) and ribavirin [2]

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. October 2022. http://www.hcvguidelines.org/full-report-view. Accessed May 14, 2023.

4 . Revision History

Date	Notes
6/6/2023	Annual review - no criteria changes; background updates

Sprycel (dasatinib)

Prior Authorization Guideline

Guideline ID	GL-126741
Guideline Name	Sprycel (dasatinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 02/16/2023 ; 05/18/2023 ; 7/19/2023

1 . Indications

Drug Name: Sprycel (dasatinib)
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. **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. **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. **Pediatric ALL** Indicated for the treatment of pediatric patients 1 year of age and older with newly diagnosed Ph+ ALL in combination with chemotherapy. **Pediatric Patients with Ph+ CML** Indicated for the treatment of pediatric patients 1 year of age and older with Ph+ CML in chronic phase.

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
Approval Criteria **1** - Diagnosis of Ph+/BCR ABL acute lymphoblastic leukemia (ALL)	

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

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)

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 . 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.

4 . Revision History

Date	Notes
6/15/2023	Removal of specialist requirement

Stelara (ustekinumab)

Prior Authorization Guideline

Guideline ID	GL-137221
Guideline Name	Stelara (ustekinumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/16/2010
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022 ; 09/20/2023 ; 9/20/2023

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

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

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)

Product Name: Stelara SC	
Diagnosis	Plaque Psoriasis
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 ONE of the following [1-3]:

- 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

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 - Patient is 6 years of age or older

AND

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

- 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 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:

- 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

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, 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

Approval Criteria

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

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 (CDAI) 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

Approval Criteria

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

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 IV	
Diagnosis	Ulcerative Colitis
Approval Length	1 Time(s)
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 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 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 5-8]:

- 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.

4 . Revision History

Date	Notes
11/30/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Stivarga (regorafenib)

Prior Authorization Guideline

Guideline ID	GL-127568
Guideline Name	Stivarga (regorafenib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	12/18/2019 ; 06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 05/18/2023 ; 06/21/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of metastatic colorectal cancer (mCRC)

Product Name: Stivarga	
Diagnosis	Gastrointestinal Stromal Tumor (GIST) [1,2]
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 one of the following:

- Locally advanced
- Unresectable
- Metastatic

Product Name: Stivarga	
Diagnosis	Hepatocellular Carcinoma (HCC) [1,2]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
Approval Criteria **1** - Diagnosis of hepatocellular carcinoma (HCC)	

Product Name: Stivarga	
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. 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.

4 . Revision History

Date	Notes
7/5/2023	Removed specialist requirement

Strensiq (asfotase alfa)

Prior Authorization Guideline

Guideline ID	GL-127143
Guideline Name	Strensiq (asfotase alfa)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 11/18/2021 ; 07/20/2022 ; 10/19/2022 ; 4/15/2023

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 criteria above are met and the 80mg strength is requested, see table in the Background Section for auth approval instructions. For all other strengths, approve auth at GPI-14 level if criteria above are met.

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 criteria above are met and the 80mg strength is requested, see table in the Background Section for auth approval instructions. For all other strengths, approve auth at GPI-14 level if criteria above are met.

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 as medical necessity.

3 . Background

Benefit/Coverage/Program Information

80 mg/0.8 mL Vial Approval Instructions:

Please enter 2 PAs as follows with the same start date:

Member Weight	First PA	Second PA
40 to 74 kg	Approve 12 vials (9.6 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).
75 to 119 kg	Approve 24 vials (19.2 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).
Greater than or equal to 120 kg	Approve 36 vials (28.8 mL) per 28 days at GPI-14.	Approve at GPI-12 (no overrides needed).

4 . 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]

5 . 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, Odrljin 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. 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

6 . Revision History

Date	Notes
6/27/2023	2023 Annual Review

Sucraid (sacrosidase) Oral Solution

Prior Authorization Guideline

Guideline ID	GL-135758
Guideline Name	Sucraid (sacrosidase) Oral Solution

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/14/2022
P&T Revision Date:	04/19/2023 ; 4/19/2023

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 - Patient demonstrates 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.

4 . Revision History

Date	Notes
11/1/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Sutent (sunitinib) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127116
Guideline Name	Sutent (sunitinib) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/1/2006
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 10/20/2021 ; 03/16/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Sutent (sunitinib)
Gastrointestinal stromal tumor (GIST) Indicated for the treatment of adult patients gastrointestinal stromal tumor (GIST) 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 (pNET) in patients with unresectable locally advanced or metastatic disease. **Advanced renal cell carcinoma** Indicated for the treatment of adult patients with 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

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - History of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Gastrointestinal Stromal Tumor (GIST)
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	Gastrointestinal Stromal Tumor (GIST)

Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of gastrointestinal stromal tumor (GIST)

AND

2 - Paid claims or submission of medical records (e.g., chart notes) confirming history of disease progression, contraindication, or intolerance to Gleevec (imatinib)

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to generic sunitinib

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Pancreatic Neuroendocrine Tumors (pNET)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

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

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)

Product Name: Brand Sutent, Generic sunitinib	
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

Product Name: Brand Sutent	
Diagnosis	Advanced Renal Cell Carcinoma
Approval Length	12 month(s)
Guideline Type	Non Formulary

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

Product Name: Brand Sutent, Generic sunitinib	
Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

AND

2 - Used as adjuvant therapy

AND

3 - Patient is at high risk of recurrent RCC following nephrectomy

AND

4 - Trial and failure or intolerance to generic sunitinib (applies to Brand Sutent only)

Product Name: Brand Sutent

Diagnosis	Adjuvant Treatment of Renal Cell Carcinoma
Approval Length	12 Months [A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of renal cell carcinoma (RCC)

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

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. August 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.

5 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Syfovre (pegcetacoplan)

Prior Authorization Guideline

Guideline ID	GL-135003
Guideline Name	Syfovre (pegcetacoplan)

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Syfovre (pegcetacoplan)
Geographic Atrophy (GA) Indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).

2 . Criteria

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

1 - Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) as confirmed by one of the following:

- Fundus photography (e.g. fundus autofluorescence [FAF])
- Optical coherence tomography (OCT)
- Fluorescein angiography

AND

2 - GA is not secondary to any other conditions (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)

AND

3 - Prescribed by or in consultation with an ophthalmologist experienced in the treatment of retinal diseases

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in growth rate of GA lesion)

3 . References

1. Syfovre Prescribing Information. Apellis Pharmaceuticals, Inc. Waltham, MA. February 2023.

4 . Revision History

Date	Notes
10/16/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Synagis (palivizumab)

Prior Authorization Guideline

Guideline ID	GL-135551
Guideline Name	Synagis (palivizumab)

Guideline Note:

Effective Date:	11/17/2023
P&T Approval Date:	3/17/2000
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 09/20/2023 ; 11/16/2023

1 . Indications

Drug Name: Synagis (palivizumab)
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.

2 . Criteria

Product Name: Synagis

Diagnosis	Premature Infants (without other indications)
Approval Length	5 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Born prematurely at or before 29 weeks, 0 days gestation [2, B]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season [A].

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 - Patient has not received Beyfortus (nirsevimab) for the current RSV season [4]

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, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

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 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

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 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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 postoper ative dose allowed for patients undergoing cardiac transplantation, car diac 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/nrevss/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

Approval Criteria

1 - Pulmonary abnormalities (e.g., pulmonary malformations, tracheoesophageal fistula, conditions requiring tracheostomy) or neuromuscular disease (e.g., cerebral palsy) [2]

AND

2 - Age < 12 months at the start of the respiratory syncytial virus (RSV) season.

AND

3 - Impaired ability to clear secretions from the upper airway due to an ineffective cough

AND

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

- Pediatric pulmonologist
- Neurologist

AND

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

AND

6 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

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 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

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, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.

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

<table>
<tr><td colspan="2">

- 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 - Patient has not received Beyfortus (nirsevimab) for the current RSV season

</td></tr>
<tr><td>Notes</td><td>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, refe r to the CDC surveillance reports (http://www.cdc.gov/surveillance/nre vss/rsv/index.html) to confirm the start of RSV season based on regio n.</td></tr>
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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 coaractation 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. Commitee 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

5 . Revision History

Date	Notes
10/30/2023	Updated criteria for not take in combination with Beyfortus to "Patient has not received Beyfortus for the current RSV season"

Synribo (omacetaxine mepesuccinate)

Prior Authorization Guideline

Guideline ID	GL-131183
Guideline Name	Synribo (omacetaxine mepesuccinate)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/19/2013
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 05/18/2023 ; 06/21/2023 ; 6/21/2023

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

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.

5 . Revision History

Date	Notes
8/21/2023	Removed prescriber requirement

Tabrecta (capmatinib) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127299
Guideline Name	Tabrecta (capmatinib) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/15/2020
P&T Revision Date:	11/12/2020 ; 11/12/2020 ; 06/16/2021 ; 06/15/2022 ; 06/21/2023 ; 7/19/2023

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	
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 positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Tabrecta	
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: Tabrecta	
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 positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

OR

1.2 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. Tabrecta Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. March 2023.

4 . Revision History

Date	Notes
6/29/2023	Removed specialist requirement

Tafinlar (dabrafenib)

Prior Authorization Guideline

Guideline ID	GL-134078
Guideline Name	Tafinlar (dabrafenib)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 08/18/2022 ; 03/15/2023 ; 07/19/2023 ; 10/18/2023

1 . Indications

Drug Name: Tafinlar (dabrafenib)
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. **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. **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. **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

Anaplastic thyroid cancer (ATC) with BRAF V600E mutation Indicated in combination with 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 1 year 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

Approval Criteria

1 - One of the following diagnoses: [2]

- Unresectable melanoma
- Metastatic melanoma

AND

2 - One of the following:

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]

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)
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	Unresectable or metastatic solid tumors
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of solid tumors

AND

2 - Patient is 1 year 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: Tafinlar	
Diagnosis	Low-grade glioma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of low-grade glioma

AND

2 - Patient is 1 year of age or older

AND

3 - Patient requires systemic therapy

AND

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)

AND

5 - Medication is used in combination with Mekinist (trametinib)

Product Name: Tafinlar

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. August 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.

5 . Revision History

Date	Notes
10/2/2023	update guideline

Tagrisso (osimertinib)

Prior Authorization Guideline

Guideline ID	GL-126919
Guideline Name	Tagrisso (osimertinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	1/27/2016
P&T Revision Date:	04/15/2020 ; 02/18/2021 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

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 Both 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)

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

Notes	*This product may require prior authorization.

Product Name: Tagrisso	
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. Tagrisso prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2022.
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.
3. National comprehensive cancer network (NCCN). Clinical practice guidelines in oncology. Non-small cell lung cancer. v.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.

4 . Revision History

Date	Notes
6/21/2023	Removed Oncology specialist requirement

Taltz (ixekizumab)

Prior Authorization Guideline

Guideline ID	GL-134282
Guideline Name	Taltz (ixekizumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/19/2016
P&T Revision Date:	09/18/2019 ; 10/16/2019 ; 11/14/2019 ; 05/14/2020 ; 08/13/2020 ; 09/16/2020 ; 07/21/2021 ; 03/16/2022 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022 ; 12/14/2022 ; 01/18/2023 ; 07/19/2023 ; 7/19/2023

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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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 - Patient demonstrates positive clinical response to therapy as evidenced by ONE of the following [1-3]:

- 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

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

- Dermatologist
- Rheumatologist

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to ONE 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)

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 - 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, 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

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 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), Amjevita, Cyltezo, Hyrimoz, or Brand Adalimumab-adaz
- 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 be en tried in the past, and the patient should not be made to try a third T NF inhibitor.

Product Name: Taltz	
Diagnosis	Ankylosing Spondylitis
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 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: Taltz	
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 - 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 Trial and failure, contraindication, or intolerance to ONE of the following:

- Cimzia (certolizumab pegol)
- Rinvoq (upadacitinib)

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 - Patient demonstrates 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

3 . References

1. Taltz prescribing information. Eli Lilly and Company. Indianapolis, IN. 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.
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.

4 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Tarceva (erlotinib)

Prior Authorization Guideline

Guideline ID	GL-127549
Guideline Name	Tarceva (erlotinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/14/2003
P&T Revision Date:	06/19/2019 ; 04/15/2020 ; 04/21/2021 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Tarceva (erlotinib)
Non-Small Cell Lung Cancer (NSCLC) Indicated for 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 receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen. **Pancreatic Cancer** Indicated for the first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer in combination with gemcitabine.

2 . Criteria

Product Name: Brand Tarceva, Generic erlotinib

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 U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) [2]

Product Name: Brand Tarceva, Generic erlotinib	
Diagnosis	Pancreatic Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Locally advanced pancreatic cancer
- Unresectable pancreatic cancer
- Metastatic pancreatic cancer

AND

2 - Used in combination with Gemzar (gemcitabine)

Product Name: Brand Tarceva, Generic erlotinib	
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. 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.3.2022. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed March 27, 2023.
3. Erlotinib Prescribing Information. Mylan Pharmaceuticals. Morgantown, WV. January 2019.

4 . Revision History

Date	Notes
7/5/2023	update guideline

Targretin (bexarotene)

Prior Authorization Guideline

Guideline ID	GL-128510
Guideline Name	Targretin (bexarotene)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	11/17/2009
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 08/13/2020 ; 08/19/2021 ; 07/20/2022 ; 08/18/2022 ; 8/17/2023

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

Approval Criteria

1 - Diagnosis of cutaneous T-cell lymphoma (CTCL) [A]

AND

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])

AND

3 - Trial and failure, contraindication, or intolerance to generic Targretin (Applies to brand Targretin only)

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

Approval Criteria

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

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.

5 . Revision History

Date	Notes
8/8/2023	Annual Review

Tasigna (nilotinib)

Prior Authorization Guideline

Guideline ID	GL-126877
Guideline Name	Tasigna (nilotinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	12/18/2019 ; 04/15/2020 ; 04/21/2021 ; 11/18/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of Philadelphia chromosome-positive/BCR ABL positive (Ph+/BCR ABL) chronic myelogenous/myeloid leukemia (CML) (A)

AND

2 - Patient is 1 year of age or older

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to generic imatinib

OR

3.2 Continuation of prior therapy

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.

5 . Revision History

Date	Notes
6/20/2023	Removal of specialist requirement

Tavneos (avacopan) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-134352
Guideline Name	Tavneos (avacopan) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/15/2021
P&T Revision Date:	04/20/2022 ; 11/17/2022 ; 11/16/2023

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

Approval Criteria

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

AND

2 - Patient is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab)

AND

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

- Nephrologist
- Pulmonologist
- Rheumatologist

Product Name: Tavneos	
Approval Length	12 month(s)
Guideline Type	Non Formulary

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 - 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 2022. Accessed October 9, 2022.
5. Merkel PA, Kaplan AA. Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy. UpToDate 2022. Accessed October 9, 2022.

4 . Revision History

Date	Notes
10/5/2023	2023 Annual Review

Tecfidera (dimethyl fumarate) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-135833
Guideline Name	Tecfidera (dimethyl fumarate) - PA, NF

Guideline Note:

Effective Date:	11/3/2023
P&T Approval Date:	6/16/2021
P&T Revision Date:	05/19/2022 ; 5/19/2022

1 . Indications

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.

2 . Criteria

Product Name: Brand Tecfidera	
Approval Length	12 month(s)
Guideline Type	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) [3]

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate) [A, 5]

AND

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

AND

4 - 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	
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) [3]

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting failure after a trial of at least 4 weeks, or intolerance to both of the following:

- generic dimethyl fumarate
- Bafiertam (monomethyl fumarate)

AND

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

AND

4 - 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

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

3 . Endnotes

A. Although the trial results of Bafiertam was based off of Tecfidera, the consultant thinks that the two drugs should have the same efficacy and safety profile since Bafiertam was 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. February 2022.
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.

5 . Revision History

Date	Notes
11/2/2023	Updated brand Tecfidera starter pack, generic dimethyl fumarate star ter pack gpi.

Temodar (temozolomide)

Prior Authorization Guideline

Guideline ID	GL-135355
Guideline Name	Temodar (temozolomide)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/9/2013
P&T Revision Date:	08/15/2019 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 05/18/2023 ; 07/19/2023 ; 11/16/2023

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. **Anaplastic Astrocytoma** Indicated for the adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma and treatment of adults with refractory anaplastic astrocytoma.

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

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

3 . References

1. Temodar Prescribing Information, Merck & Co, Inc. Whitehouse Station, NJ. September 2023.
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.

4 . Revision History

Date	Notes
11/1/2023	Update to Indications. Updated references.

Tepmetko (tepotinib) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127617
Guideline Name	Tepmetko (tepotinib) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/21/2021
P&T Revision Date:	07/21/2021 ; 12/15/2021 ; 04/20/2022 ; 04/19/2023 ; 7/19/2023

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 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to Tabrecta

OR

4.2 For continuation of prior therapy

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 - 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 - 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 Tabrecta

OR

4.2 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 . 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.

5 . Revision History

Date	Notes
7/6/2023	Removed specialist requirement

Teriparatide Products

Prior Authorization Guideline

Guideline ID	GL-125559
Guideline Name	Teriparatide Products

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	1/3/2003
P&T Revision Date:	01/19/2022 ; 6/21/2023

1 . Indications

Drug Name: Forteo (teriparatide injection), Teriparatide (teriparatide 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, teriparatide reduces the risk of vertebral and nonvertebral fractures. **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. **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.

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

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 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 - 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) 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)

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

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 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) 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)

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) 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)

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

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 - 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) 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)

Product Name: Brand Teriparatide

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

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) 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)

Product Name: Forteo, Brand Teriparatide

Diagnosis	Primary or hypogonadal 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) 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)

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

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

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]

AND

3 - One of the following: [8,A]

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) [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) 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)

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

Approval Criteria

1 - Diagnosis of glucocorticoid-induced osteoporosis

AND

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]

AND

3 - One of the following: [8,A]

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) [E]

AND

5 - One of the following: [7,B]

5.1 Treatment duration of parathyroid hormones (e.g., teriparatide) 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)

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) 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)

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.

4 . Endnotes

A. According to the American College of Rheumatology (ACR) guidelines for the prevention and treatment of glucocorticoid-induced osteoperosis, 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. Per clinical consultation with endocrinologists. January 23 & 30, 2018.
8. 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.
9. 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.
10. Teriparatide prescribing information. Alvogen, Inc. Morristown, NJ. November 2019.

6 . Revision History

Date	Notes
5/12/2023	2023 UM Annual Review. Added in "For diagnosis of osteoporosis" a nd "For diagnosis of osteopenia" to align with Tymlos. No change to clinical intent. Updated criteria for GIC to align with 2022 update from

	ACR to include GC dosing of at least 30 mg or cumulative GC dose of at least 5 grams per year for high risk stratification of patients.

Thalomid (thalidomide)

Prior Authorization Guideline

Guideline ID	GL-137224
Guideline Name	Thalomid (thalidomide)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/22/2007
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Thalomid (thalidomide)
Erythema Nodosum Leprosum (ENL) Indicated for the acute treatment of the cutaneous manifestations of moderate to severe ENL. Not indicated as monotherapy for such ENL treatment in the presence of moderate to severe neuritis. Also indicated as a maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence. **Newly Diagnosed Multiple Myeloma** Indicated in combination with dexamethasone for the treatment of patients with newly diagnosed multiple myeloma.

2 . Criteria

Product Name: Thalomid	
Diagnosis	Erythema Nodosum Leprosum (ENL)

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of multiple myeloma

AND **2** - Used in combination with dexamethasone, unless the patient has an intolerance to steroids

Product Name: Thalomid	
Diagnosis	Multiple Myeloma
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. Thalomid Prescribing Information. Celgene Corporation. Summit, NJ. December 2022.

4 . Revision History

Date	Notes
11/30/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Thyrogen (thyrotropin alfa for injection)

Prior Authorization Guideline

Guideline ID	GL-105253
Guideline Name	Thyrogen (thyrotropin alfa for injection)

Guideline Note:

Effective Date:	6/1/2022
P&T Approval Date:	1/19/2001
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 4/20/2022

1 . Indications

Drug Name: Thyrogen (thyrotropin alfa for injection)
Adjunctive Diagnostic Tool for Serum Thyroglobulin Testing in Well Differentiated Thyroid Cancer Indicated for use as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer who have previously undergone thyroidectomy. Limitations of Use: Thyrogen-stimulated Tg levels are generally lower than, and do not correlate with, Tg levels after thyroid hormone withdrawal. Even when Thyrogen-stimulated Tg testing is performed in combination with radioiodine imaging, there remains a risk of missing a diagnosis of thyroid cancer or of underestimating the extent of disease. Anti-Tg antibodies may confound the Tg assay and render Tg levels uninterpretable. Therefore, in such cases, even with a negative or low-stage Thyrogen radioiodine scan, consideration should be given to further evaluating patients. **Adjunct to Treatment for Ablation in Well Differentiated Thyroid Cancer** Indicated for use as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer. Limitations of Use: The effect of Thyrogen on long-term thyroid cancer outcomes has not been determined. Due to the relatively small clinical experience with Thyrogen in remnant ablation, it is not possible to

conclude whether long-term thyroid cancer outcomes would be equivalent after use of Thyrogen or use of thyroid hormone withholding for TSH elevation prior to remnant ablation.

2 . Criteria

Product Name: Thyrogen	
Approval Length	1 course of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Thyrogen is being used as a diagnostic tool for serum thyroglobulin testing in well differentiated thyroid cancer

OR

1.2 All of the following:

1.2.1 Thyrogen is being used as an adjunctive treatment for radioiodine ablation of thyroid tissue remnants

AND

1.2.2 Patient has undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer

AND

1.2.3 Patient does not have evidence of distant metastatic thyroid cancer

AND

2 - One of the following:

2.1 Patient is unable to tolerate thyroid hormone withdrawal (ie, intolerable hypothyroid symptoms) [1,2]

OR

2.2 Thyroid hormone withdrawal is medically contraindicated (ie, exacerbation of comorbid conditions) [1,2]

OR

2.3 Patient has inadequate thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal [1]

OR

2.4 Patient has an undetectable Tg on thyroid hormone suppressive therapy, to exclude the diagnosis of residual or recurrent thyroid cancer [1]

3 . References

1. Thyrogen Package Insert. Genzyme Corporation. Cambridge, MA. March 2020.
2. Cooper DS, Doherty GM, Haugen BR, et al. Revised American Thyroid Association Management Guidelines. For Patients with Thyroid Nodules and Differentiated Thyroid Cancer. Thyroid. 2009;19 (11):1167-1214.

4 . Revision History

Date	Notes
3/28/2022	2022 Annual Review - No changes to criteria, updated background in formation

Tobramycin Inhaled Products - ST, NF

Prior Authorization Guideline

Guideline ID	GL-124294
Guideline Name	Tobramycin Inhaled Products - ST, NF

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	5/21/2013
P&T Revision Date:	04/15/2020 ; 12/16/2020 ; 01/20/2021 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 5/18/2023

1 . Indications

Drug Name: Bethkis (tobramycin) Inhalation Solution
Cystic Fibrosis Indicated for the management of cystic fibrosis patients with Pseudomonas aeruginosa. 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 Burkholderia cepacia.
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 P. aeruginosa. Safety and efficacy have not been demonstrated in patients under the age of 6 years, patients with FEV1 less than 25% or greater than 75% predicted, or patients colonized with Burkholderia cepacia.
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 Pseudomonas aeruginosa. Safety and efficacy have not been

demonstrated in patients under the age of 6 years, patients with forced expiratory volume in 1 second (FEV1) <25% or >75% predicted, or patients colonized with Burkholderia cepacia.

2 . Criteria

Product Name: Brand Bethkis Inhalation Solution, Kitabis Pak, Brand TOBI Inhalation Solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

2 - Trial and failure of a minimum 30 day supply, or intolerance to both of the following:

- 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

Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication.

AND

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:

- 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. April 2023.
2. TOBI Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. February 2023.
3. Bethkis Prescribing Information. Chiesi USA, Inc. Woodstock, IL. February 2023.

4 . Revision History

Date	Notes
5/5/2023	Annual review: No criteria changes. Updated indications and references. Attached EHB formulary.

Tolvaptan Products

Prior Authorization Guideline

Guideline ID	GL-134284
Guideline Name	Tolvaptan Products

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/21/2021
P&T Revision Date:	02/17/2022 ; 04/20/2022 ; 04/19/2023 ; 4/19/2023

1 . Indications

Drug Name: Samsca (tolvaptan)
Hyponatremia, hypervolemic and euvolemic Indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Important limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. It has not been established that raising serum sodium with Samsca provides a symptomatic benefit to patients.
Drug Name: Jynarque (tolvaptan)
Autosomal Dominant Polycystic Kidney Disease Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

2 . Criteria

Product Name: Brand Samsca or Generic tolvaptan	
Approval Length	30 Days [1]
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

- Diagnosis of significant euvolemic hyponatremia [1-3, A-B]
- Diagnosis of significant hypervolemic hyponatremia [1-3, A, C]

AND

2 - Treatment has been initiated or re-initiated in a hospital setting prior to discharge within the past 30 days [1, D]

AND

3 - Trial and failure or intolerance to generic tolvaptan (applies to Brand Samsca only)

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

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

3 - One of the following:

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND

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

2.1 Both of the following:

2.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

2.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

2.2 Both of the following:

2.2.1 Patient has received Jynarque for longer than 18 months

AND

2.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

AND

3 - Patient does not have a history of significant liver impairment or injury, not including uncomplicated polycystic liver disease [E]

Product Name: Jynarque	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

AND

2 - One of the following:

2.1 Patient does not have signs or symptoms consistent with hepatic injury [E]

OR

2.2 Patient has uncomplicated polycystic liver disease

AND

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

3.1 Both of the following:

3.1.1 Patient has received Jynarque for less than or equal to 18 months

AND

3.1.2 Alanine transaminase (ALT), aspartate transaminase (AST), and bilirubin will be

measured prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months of therapy [E]

OR

3.2 Both of the following:

3.2.1 Patient has received Jynarque for longer than 18 months

AND

3.2.2 ALT, AST, and bilirubin will be measured at least every 3 months [E]

3 . Endnotes

A. Normal extracellular fluid volume and osmolality are maintained when the serum sodium concentration is regulated within a narrow range (136 to 148 mEq/L). [2] Hypotonic hyponatremia, a disorder of impaired water excretion rather than salt depletion, results from the kidneys' inability to excrete enough free water to offset water intake. [2] Hypotonic hyponatremia is classified based on the patient's extracellular fluid (ECF) volume status as hypovolemic hyponatremia, euvolemic hyponatremia, or hypervolemic hyponatremia. [3] Samsca is indicated for the treatment of clinically significant euvolemic and hypervolemic hyponatremia, defined as a serum sodium of less than 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction. [1]

B. Many different hypo-osmolar disorders can potentially present clinically with a normal ECF volume, or euvolemia, in part because it is difficult to detect modest changes in volume status using standard methods of clinical assessment. [3] Most patients with hyponatremia have clinical euvolemia (most commonly associated with the syndrome of inappropriate secretion of antidiuretic hormone [SIADH] or due to other causes [e.g., hypothyroidism, adrenal insufficiency, other disorders of excess water intake]) and are generally diagnosed clinically from the history, physical examination, and laboratory results. [2-3] Patients without clinical signs of volume depletion (e.g., orthostatic decreases in blood pressure and increases in pulse rate, dry mucus membranes, decreased skin turgor) or volume expansion (e.g., subcutaneous edema, ascites) should be considered to have euvolemia unless there is alternative evidence suggesting an abnormal ECF volume status. [3] Supportive laboratory results include a normal or low blood urea nitrogen (BUN) and a low serum uric acid level. [3] A spot urine sodium concentration should be greater than or equal to 30 mmol/L in most patients with euvolemic hyponatremia unless they have become secondarily sodium depleted. [3]

C. The presence of clinically detectable increased ECF volume generally reflects hypervolemia from some degree of body sodium excess. [3] Hyponatremia with ECF volume excess can arise in a variety of diseases (e.g., congestive heart failure, cirrhosis,

renal failure). [3] Because intravascular volume cannot be easily measured directly, volume excess is generally diagnosed clinically from the history, physical examination, and laboratory results. [3] Patients with clinical signs of volume overload (e.g., subcutaneous edema, ascites, pulmonary edema) should be considered to have hypervolemia unless there are alternative explanations for these findings. [3] Elevation of plasma levels of brain natriuretic peptide (BNP) provides useful laboratory support for the presence of volume overload. [3] The urine sodium, or fractional sodium excretion, is usually low (spot urine sodium of less than 30 mmol/L) in patients with hypervolemic hyponatremia due to activation of the renin-angiotensin-aldosterone system (RAAS) with secondary renal sodium conservation despite the whole-body volume overload. [3]

D. Because of the risk of osmotic demyelination associated with overly-rapid correction of serum sodium, tolvaptan should be initiated in a hospital so that the serum sodium concentration can be monitored easily. If therapy is discontinued for any reason and the patient becomes hyponatremic, tolvaptan should be re-initiated in a hospital if further treatment with tolvaptan is indicated. "In a hospital" means anywhere in a hospital where the patient can be observed and serum sodium levels can be obtained (e.g., an emergency department, an observation unit, or an inpatient bed). [1]
E. Jynarque can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. ALT, AST and bilirubin should be monitored prior to initiation, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter. [4]

4 . References

1. Samsca Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. April 2021.
2. Ghali JK. Mechanisms, risks, and new treatment options for hyponatremia. Cardiology. 2008;11:147-157.
3. Verbalis JG, Goldsmith SR, Greenberg A, et al. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. The American Journal of Medicine. 2013;126(10 Suppl 1):S1-42.
4. Jynarque Prescribing Information. Otsuka America Pharmaceuticals, Inc. Rockville, MD. October 2020.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Trastuzumab - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127007
Guideline Name	Trastuzumab - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	9/8/2000
P&T Revision Date:	08/15/2019 ; 12/18/2019 ; 03/18/2020 ; 05/14/2020 ; 06/17/2020 ; 04/21/2021 ; 06/16/2021 ; 12/15/2021 ; 06/15/2022 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Herceptin (trastuzumab), Herzuma (trastuzumab-pkrb), Kanjinti (trastuzumab-anns), Ogivri (trastuzumab-dkst), Ontruzant (trastuzumab-dkst), Trazimera (trastuzumab-qyyp)
Adjuvant Breast Cancer Indicated for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease. **Metastatic Gastric Cancer** Indicated in combination with cisplatin and capecitabine or 5-fluorouracil, for the treatment of patients with HER2 overexpressing metastatic gastric or

gastroesophageal junction adenocarcinoma, who have not received prior treatment for metastatic disease.
Drug Name: Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)
Adjuvant Breast Cancer Indicated for adjuvant treatment of adults with HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer: 1) as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel, 2) as part of a treatment regimen with docetaxel and carboplatin, 3) as a single agent following multi-modality anthracycline based therapy. **Metastatic Breast Cancer** Indicated in adults: 1) In combination with paclitaxel for first-line treatment of HER2-overexpressing metastatic breast cancer, 2) As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease.

2 . Criteria

Product Name: Kanjinti, Trazimera	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Breast Cancer

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

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [3-5, 7, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

Product Name: Kanjinti, Trazimera	
Diagnosis	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

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric Cancer

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

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [3-5, 7, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [3-5, 7, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

Product Name: Kanjinti, Trazimera	
Diagnosis	Metastatic Gastric 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: Herceptin Hylecta	
Diagnosis	Adjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - One of the following:

2.1 Administered as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel

OR

2.2 Administered as part of a treatment regimen with docetaxel and carboplatin

OR

2.3 Administered as a single agent following multi-modality anthracycline based therapy

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin Hylecta	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following:

3.1 Administered in combination with paclitaxel for first-line treatment

OR

3.2 Administered as a single agent for treatment in patients who have received one or more chemotherapy regimens for metastatic disease

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin Hylecta	
Diagnosis	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

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Adjuvant or Neoadjuvant Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - One of the following treatment regimens: [4, C]

- Adjuvant treatment
- Used in combination with Perjeta (pertuzumab)

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 both of the following:

- Kanjinti
- Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

AND

4 - One of the following:

4.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

4.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	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

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Breast Cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing of breast cancer [A]

AND

2 - Disease is metastatic

AND

3 - One of the following treatment regimens: [1, 4-6, 8-9, C]

- Used in combination with a taxane
- Used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease
- Used in combination with Perjeta (pertuzumab)

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 both of the following:

- Kanjinti
- Trazimera

OR

4.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

AND

3 - One of the following:

3.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

3.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herceptin, Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric 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 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to both of the following:

- Kanjinti
- Trazimera

OR

2.2 Continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen

Product Name: Herzuma, Ogivri, Ontruzant	
Diagnosis	Metastatic Gastric Cancer

Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic) [1, 4-6, 8-9, A-C]

AND

2 - Used in combination with one of the following treatment regimens: [1, 4-6, 8-9, C]

- Platinol (cisplatin) and Adrucil (5-fluorouracil)
- Platinol (cisplatin) and Xeloda (capecitabine)

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 both of the following:

- Kanjinti
- Trazimera

OR

3.2 Paid claims or submission of medical records (e.g., chart notes) confirming continuation of therapy for patients currently in the midst of an ongoing prescribed treatment regimen, defined as no more than a 45-day gap in therapy

3 . Endnotes

A. Detection of HER2 protein overexpression is necessary for selection of patients appropriate for trastuzumab therapy because these are the only patients studied and for whom benefit has been shown. Due to differences in tumor histopathology, use FDA-approved tests for the specific tumor type (e.g. breast or gastric/gastroesophageal adenocarcinoma) to assess HER2 protein overexpression and HER2 gene amplification.

Assessment of HER2 protein overexpression and HER2 gene amplification should be performed using FDA-approved tests specific for breast cancer by laboratories with demonstrated proficiency. Improper assay performance, including use of suboptimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation, can lead to unreliable results. Assessment of HER2 protein overexpression and HER2 gene amplification in metastatic gastric cancer should be performed using FDA-approved tests specifically for gastric cancers due to differences in gastric vs. breast histopathology, including incomplete membrane staining and more frequent heterogeneous expression of HER2 seen in gastric cancers. Study 7 demonstrated that gene amplification and protein overexpression were not as well correlated as with breast cancer. Treatment outcomes for metastatic gastric cancer (Study 7) are based on HER2 gene amplification (FISH) and HER 2 protein overexpression (IHC) test results. [1-3, 6-9]

B. Herceptin, Kanjinti, Ogivri, Trazimera, Herzuma and Ontruzant are indicated for the treatment of HER-2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma. A pivotal study included patients previously untreated for metastatic gastric or gastroesophageal junction adenocarcinoma. [1, 3, 6-9]
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. [5]

4 . References

1. Herceptin Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2021.
2. Herceptin Hylecta Prescribing Information. Genentech, Inc. South San Francisco, CA. February 2019.
3. Kanjinti Prescribing Information. Amgen Inc. Thousand Oaks, CA. October 2019.
4. The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at www.nccn.org. Accessed May 15, 2023.
5. U.S. Food and Drug Administration (FDA). Biosimilar and Interchangeable Products. Silver Spring, MD: FDA; October 23, 2017. Available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm580419.htm#biosimilar. Accessed May 14, 2021.
6. Ogivri Prescribing Information. Mylan Institutional LLC. Rockford, IL. February 2021.
7. Trazimera Prescribing Information. Pfizer Laboratories Div Pfizer Inc. New York, NY. November 2020.
8. Herzuma Prescribing Information. Celltrion, Inc. Incheon, Republic of Korea. May 2019.
9. Ontruzant Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. March 2020.

5 . Revision History

Date	Notes

6/22/2023	Removed Oncology specialist requirement

Tremfya (guselkumab)

Prior Authorization Guideline

Guideline ID	GL-121713
Guideline Name	Tremfya (guselkumab)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	9/27/2017
P&T Revision Date:	03/18/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 10/19/2022 ; 3/15/2023

1 . Indications

Drug Name: Tremfya (guselkumab)
Plaque Psoriasis (PsO) 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 (PsO)
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

Product Name: Tremfya	
Diagnosis	Plaque Psoriasis (PsO)
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]:

- Reduction the body surface area (BSA) involvement from baseline
- Improvement in symptoms (e.g., pruritus, inflammation) from baseline

Product Name: Tremfya	
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 (PsA)

AND

2 - One of the following [4]:

- 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: Tremfya	
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

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. 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.

4 . Revision History

Date	Notes
2/26/2023	Annual review - no criteria changes; background updates

Tukysa (tucatinib)

Prior Authorization Guideline

Guideline ID	GL-127573
Guideline Name	Tukysa (tucatinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/17/2020
P&T Revision Date:	06/16/2021 ; 06/15/2022 ; 03/15/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Tukysa (tucatinib)
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. **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.

2 . Criteria

Product Name: Tukysa	
Diagnosis	Breast Cancer
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 unresectable
- Metastatic

AND

3 - Disease is human epidermal growth factor receptor 2 (HER2)-positive

AND

4 - Used in combination with trastuzumab and capecitabine

AND

5 - Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)

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

Product Name: Tukysa	
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. Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. January 2023.

4 . Revision History

Date	Notes
7/5/2023	Removed specialist requirement

Turalio (pexidartinib)

Prior Authorization Guideline

Guideline ID	GL-135700
Guideline Name	Turalio (pexidartinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/18/2019
P&T Revision Date:	09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 03/15/2023 ; 07/19/2023 ; 11/16/2023

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

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.

4 . Revision History

Date	Notes
11/1/2023	Annual Review, no changes.

Tykerb (lapatinib)

Prior Authorization Guideline

Guideline ID	GL-131985
Guideline Name	Tykerb (lapatinib)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	5/22/2007
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 11/12/2020 ; 09/15/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

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. Limitations of use: Patients should have disease progression on trastuzumab prior to initiation of treatment with Tykerb in combination with capecitabine.; (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

Approval Criteria

1 - Diagnosis of HER2-positive metastatic or recurrent breast cancer [2-6]

AND

2 - Used in combination with one of the following: [3]

- Trastuzumab
- Xeloda (capecitabine)
- Aromatase inhibitors [e.g., Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]

Product Name: Brand Tykerb, generic lapatinib	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient does not show evidence of progressive disease

3 . References

1. Tykerb Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. August 2023.
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 26, 2022.
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. June 2022.

4 . Revision History

Date	Notes
8/30/2023	2023 UM Annual review. No criteria changes. Updated references

Tysabri (natalizumab)

Prior Authorization Guideline

Guideline ID	GL-134285
Guideline Name	Tysabri (natalizumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/20/2000
P&T Revision Date:	05/14/2020 ; 01/20/2021 ; 05/20/2021 ; 05/19/2022 ; 10/19/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Tysabri (natalizumab)
Multiple Sclerosis (MS) Indicated as monotherapy for the treatment of 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 disease, 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)
- Lemtrada (alemtuzumab)
- Mavenclad (cladribine)
- Plegridy (peginterferon beta-1a)
- 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)

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

Product Name: Tysabri	
Diagnosis	Multiple Sclerosis (MS)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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: 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 rapeutic benefit by 12 weeks of induction therapy, and in patients that cannot discontinue chronic concomitant steroids within six months of s tarting 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 - Patient demonstrates 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. April 2023.
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.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Ultomiris (ravulizumab-cwvz)

Prior Authorization Guideline

Guideline ID	GL-137228
Guideline Name	Ultomiris (ravulizumab-cwvz)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/14/2019
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 12/16/2020 ; 03/17/2021 ; 08/19/2021 ; 03/16/2022 ; 09/21/2022 ; 03/15/2023 ; 3/15/2023

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

Approval Criteria

1 - Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

AND

2 - Patient is one month of age and older

AND

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

Product Name: Ultomiris	
Diagnosis	Paroxysmal Nocturnal Hemoglobinuria (PNH)
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., hemoglobin stabilization, decrease in the number of red blood cell transfusions) to therapy

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 - Patient demonstrates positive clinical response to therapy (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
Approval Criteria **1** - Patient demonstrates positive clinical response to therapy	

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.

4 . Revision History

Date	Notes
11/30/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Unituxin (dinutuximab)

Prior Authorization Guideline

Guideline ID	GL-126988
Guideline Name	Unituxin (dinutuximab)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	5/20/2015
P&T Revision Date:	06/17/2020 ; 02/18/2021 ; 06/16/2021 ; 7/19/2023

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)

3 . References

1. Unituxin Prescribing Information. United Therapeutics Corp. Research Triangle Park, NC. October 2020.

4 . Revision History

Date	Notes
6/22/2023	Removed specialist requirement

Venclexta (venetoclax)

Prior Authorization Guideline

Guideline ID	GL-127516
Guideline Name	Venclexta (venetoclax)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	6/22/2016
P&T Revision Date:	07/17/2019 ; 02/13/2020 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 03/15/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

Product Name: Venclexta	
Diagnosis	Acute Myeloid Leukemia (AML)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of AML

AND

2 - Disease is one of the following:

- Newly diagnosed
- Relapsed
- Refractory

Product Name: Venclexta	
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. 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.

4 . Revision History

Date	Notes
7/3/2023	Removed specialist requirement

Veopoz (pozelimab-bbfg)

Prior Authorization Guideline

Guideline ID	GL-137537
Guideline Name	Veopoz (pozelimab-bbfg)

Guideline Note:

Effective Date:	1/1/2024

1 . Indications

Drug Name: Veopoz (pozelimab-bbfg)
CD55-deficient protein-losing enteropathy (PLE) Indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

2 . Criteria

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

1 - Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease

AND

2 - Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation

AND

3 - Patient is 1 year of age or older

AND

4 - Patient has hypoalbuminemia (serum albumin concentration of less than or equal to 3.2 g/dL)

AND

5 - Patient has at least one of the following signs or symptoms within the last six months:

- abdominal pain
- diarrhea
- peripheral edema
- facial edema

AND

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

- Immunologist
- Geneticist
- Hematologist
- Gastroenterologist

Product Name: Veopoz

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 albumin transfusions and hospitalizations, normalization of serum IgG concentrations, etc.)

3 . References

1. Veopoz Prescribing Information. Regeneron Pharmaceuticals, Inc. Tarrytown, NY. August 2023.

4 . Revision History

Date	Notes
12/8/2023	Addition of EHB formulary. No changes to criteria.

Vimizim (elosulfase alfa)

Prior Authorization Guideline

Guideline ID	GL-127087
Guideline Name	Vimizim (elosulfase alfa)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 08/18/2022 ; 7/19/2023

1 . Indications

Drug Name: Vimizim (elosulfase alfa)
Mucopolysaccharidosis type IVA Indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome).

2 . Criteria

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

Approval Criteria

1 - Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) confirmed by both of the following: [1-3]

1.1 Documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.)

AND

1.2 Documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS

Product Name: Vimizim	
Approval Length	24 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy

3 . References

1. Vimizim prescribing information. BioMarin Pharmaceutical Inc. Novato, CA. December 2019.
2. UptoDate. Mucopolysaccharidoses: Clinical features and diagnosis. Available at https://www.uptodate.com/contents/mucopolysaccharidoses-clinical-features-and-diagnosis?search=Mucopolysaccharidoses:%20clinical%20features%20and%20diagnosis.%20&source=search_result&selectedTitle=1~66&usage_type=default&display_rank=1. Accessed July 6, 2022.
3. Mucopolysaccharidosis IV. Available at https://rarediseases.org/rare-diseases/morquio-syndrome/#:~:text=Excessive%20amounts%20of%20keratan%20sulfate,to%20identify%20GALNS%20gene%20mutations. Accessed July 6, 2022.

4 . Revision History

Date	Notes
7/6/2023	Updated guideline

Votrient (pazopanib)

Prior Authorization Guideline

Guideline ID	GL-136539
Guideline Name	Votrient (pazopanib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/16/2010
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 08/18/2022 ; 03/15/2023 ; 06/21/2023 ; 07/19/2023 ; 12/13/2023

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: Brand Votrient, Generic pazopanib	
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

Product Name: Brand Votrient, Generic pazopanib	
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

Product Name: Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of advanced soft tissue sarcoma (STS) [4, A]

Product Name: Brand Votrient, Generic pazopanib	
Diagnosis	Soft tissue sarcoma (STS)
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. 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.

5 . Revision History

Date	Notes
11/23/2023	Addition of generic Votrient, PA applied.

Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Prior Authorization Guideline

Guideline ID	GL-125437
Guideline Name	Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)
Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) Indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization

2 . Criteria

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

Approval Criteria

1 - Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM)

AND

2 - One of the following: [3, 4]

2.1 Patient has a transthyretin (TTR) mutation (e.g., V122I)

OR

2.2 Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits

OR

2.3 All of the following:

- Echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis
- Scintigraphy scan suggestive of cardiac TTR amyloidosis
- Absence of light-chain amyloidosis

AND

3 - One of the following: [2]

- History of heart failure, with at least one prior hospitalization for heart failure
- Presence of clinical signs and symptoms of heart failure (e.g., dyspnea, edema)

AND

4 - Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure [2]

AND

5 - Prescribed by or in consultation with a cardiologist

Product Name: Vyndaqel, Vyndamax	
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 continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure

AND

3 - Prescribed by or in consultation with a cardiologist

3 . References

1. Vyndaqel and Vyndamax prescribing information. Pfizer, Inc. New York, NY. April 2023.
2. Mauer MS, Schwartz JH, Gundapeneni B, et al. Tafamadis treatment for patients with transthyretin amyloid cardiomyopathy. N Engl J Med. 2018; 379:1007-16.
3. Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy diagnosis of cardiac transthyretin amyloidosis. Circulation. 2016; 133:2404-12.
4. Nativi-Nicolau J and Maurer MS. Amyloidosis cardiomyopathy: update in the diagnosis and treatment of the most common types. Curr Opin Cardiol. 2018; 33(5):571-579.

4 . Revision History

Date	Notes
5/8/2023	2023 UM Annual Review. No criteria changes. Update references

Vyxeos (daunorubicin and cytarabine)

Prior Authorization Guideline

Guideline ID	GL-127456
Guideline Name	Vyxeos (daunorubicin and cytarabine)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	9/27/2017
P&T Revision Date:	06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 7/19/2023

1 . Indications

Drug Name: Vyxeos (daunorubicin and cytarabine)
Newly-diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC) Indicated for the treatment of newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in adults and pediatric patients 1 year and older.

2 . Criteria

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

Approval Criteria

1 - One of the following diagnoses: [1-3]

- Newly-diagnosed therapy-related acute myeloid leukemia (t-AML)
- Newly-diagnosed acute myeloid leukemia with myelodysplasia-related changes (AML-MRC)

Product Name: Vyxeos	
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. Vyxeos Prescribing Information. Jazz Pharmaceuticals. Palo Alto, CA. April 2021.
2. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available by subscription at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 28,2021.
3. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Acute Myeloid Leukemia v.3.2021. Available by subscription at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed May 28, 2021.

4 . Revision History

Date	Notes
7/3/2023	Removed specialist requirement

Xalkori (crizotinib)

Prior Authorization Guideline

Guideline ID	GL-127124
Guideline Name	Xalkori (crizotinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	11/15/2011
P&T Revision Date:	05/14/2020 ; 02/18/2021 ; 05/20/2021 ; 05/19/2022 ; 09/21/2022 ; 06/21/2023 ; 7/19/2023

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

Approval Criteria

1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)

AND

2 - Disease is one of the following:

- Relapsed
- Refractory

AND

3 - Patient is 1 year of age or older

AND

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)

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)

AND

2 - Disease is one of the following:

- Unresectable
- Recurrent
- Refractory

AND

3 - Patient is 1 year of age or older

AND

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)

Product Name: Xalkori	
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. Xalkori Prescribing Information. Pfizer Labs. New York, NY. July 2022.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium). Available at www.nccn.org. Accessed August 12, 2022.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Xeljanz, Xeljanz XR (tofacitinib)

Prior Authorization Guideline

Guideline ID	GL-135972
Guideline Name	Xeljanz, Xeljanz XR (tofacitinib)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/19/2013
P&T Revision Date:	09/18/2019 ; 11/14/2019 ; 02/13/2020 ; 05/14/2020 ; 09/16/2020 ; 12/16/2020 ; 03/17/2021 ; 09/15/2021 ; 03/16/2022 ; 04/20/2022 ; 06/15/2022 ; 09/21/2022 ; 10/19/2022 ; 12/14/2022 ; 07/19/2023 ; 07/19/2023 ; 10/18/2023

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).

Product Name: Xeljanz tablets and oral solution	
Diagnosis	Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

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).

Product Name: Xeljanz tablets or Xeljanz XR tablets	
Diagnosis	Psoriatic 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, 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

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	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, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (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, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (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

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following [1, 7, 8]:

- 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 other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine)*	
Notes	*Xeljanz/Xeljanz XR may be used with concomitant methotrexate, topi cal or inhaled corticosteroids, and/or low stable dosages of oral cortic osteroids (equivalent to 10 mg or less of prednisone daily).

3 . Endnotes

A. 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

1. Xeljanz, Xeljanz XR Prescribing Information. Pfizer, Inc. New York, NY. January 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. 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. 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.
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.

5 . Revision History

Date	Notes
11/5/2023	12/1/23: Annual review - addition of "other JAK inhibitors" to criteria warning against concomitant use. 1/1/24: Program update to standard reauthorization language. No ch anges to clinical intent.

Xenazine (tetrabenazine)

Prior Authorization Guideline

Guideline ID	GL-137234
Guideline Name	Xenazine (tetrabenazine)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	4/6/2010
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

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 - Patient demonstrates 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

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

Product Name: Brand Xenazine, Generic tetrabenazine	
Diagnosis	Tourette's syndrome (Off-label)
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 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

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

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 - Patient demonstrates positive clinical response to therapy

3 . Endnotes

A. 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]
B. Authorization period is based on the pivotal study duration of 12 weeks. [1]
C. 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

1. Xenazine Prescribing Information. Lundbeck. Deerfield, IL. November 2019.
2. Sweet RD, Brauun 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.
3. 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.
4. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado. Available at: https://www.micromedexsolutions.com. Accessed April 1, 2021.
5. Per clinical consult with psychiatrist regarding Ingrezza (valbenazine), June 9, 2017.

5 . Revision History

Date	Notes
12/1/2023	Program update to standard reauthorization language. No changes t o clinical intent.

Xgeva (denosumab)

Prior Authorization Guideline

Guideline ID	GL-126993
Guideline Name	Xgeva (denosumab)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	4/5/2011
P&T Revision Date:	06/17/2020 ; 07/15/2020 ; 07/21/2021 ; 05/19/2022 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Xgeva (denosumab)
Multiple myeloma and Bone metastasis from solid tumors Indicated for the prevention of skeletal-related events in patients with multiple myeloma and in patients with bone metastases from solid tumors. **Giant cell tumor of bone** Indicated for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity. **Hypercalcemia of malignancy** Indicated for the treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.

2 . Criteria

Product Name: Xgeva	
Diagnosis	Skeletal prevention in multiple myeloma and bone metastasis from solid tumors (BMST)
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 Diagnosis of multiple myeloma

AND

1.1.2 Trial and failure, contraindication (e.g., renal insufficiency), or intolerance, to one intravenous bisphosphonate (e.g., zoledronic acid) [9]

OR

1.2 Both of the following:

1.2.1 Diagnosis of solid tumors (e.g., breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) [1-5]

AND

1.2.2 Documented evidence of one or more metastatic bone lesions

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of giant cell tumor of bone

AND

2 - One of the following:

2.1 Tumor is unresectable

OR

2.2 Surgical resection is likely to result in severe morbidity

Product Name: Xgeva	
Diagnosis	Giant cell tumor of bone
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 Xgeva therapy [A]

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of hypercalcemia of malignancy

AND

2 - Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g., pamidronate, zoledronic acid) [6, 7]

Product Name: Xgeva	
Diagnosis	Hypercalcemia of malignancy
Approval Length	2 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation of positive clinical response to Xgeva therapy

3 . Endnotes

A. Xgeva should be continued until disease progression in responding patients. [8]
B. Median time on the study for the treatment of hypercalcemia of malignancy was 56 days. [6]

4 . References

1. Xgeva prescribing information. Amgen Inc. Thousand Oaks, CA. June 2020.
2. Stopeck AT, Lipton A, Body JJ, et al. Denosumab compared with zoledronic acid for the treatment of bone metastases in patients with advanced breast cancer: a randomized, double-blind study. J Clin Oncol. 2010;28:5132-39.
3. Fizazi K, Carducci MA, Smith MR, et al. Denosumab versus zoledronic acid for treatment of bone metastases in men with castration-resistant prostate cancer: a randomised, double-blind study. Lancet. 2011;377(9768):813-22.
4. Henry DH, Costa L, Goldwasser F, et al. Randomized, double-blind study of denosumab versus zoledronic acid in the treatment of bone metastases in patients with advanced cancer (excluding breast and prostate cancer) or multiple myeloma. J Clin Oncol. 2011;29(9):1125-32.

5. Lipton A, Fizazi K, Stopeck AT, Henry DH, et al. Superiority of denosumab to zoledronic acid for prevention of skeletal-related events: a combined analysis of 3 pivotal, randomised, phase 3 trials. Eur J Cancer. 2012;48(16):3082-92.
6. Hu MI, Glezerman IG, Leboulleux S, et al. Denosumab for treatment of hypercalcemia of malignancy. J Clin Endocinol Metab. 2014;99(9):3144-52.
7. Stewart AF. Hypercalcemia associated with cancer. N Engl J Med. 2005; 352(4):379-9.
8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Bone Cancer v1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf. Accessed June 9, 2021.
9. National Comprehensive Cancer (NCCN) Drugs & Biologics Compendium [internet database]. Updated periodically. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 2, 2022.

5 . Revision History

Date	Notes
6/23/2023	2023 UM Annual Review. Removal of specialist requirement.

Xiaflex (collagenase clostridium histolyticum)

Prior Authorization Guideline

Guideline ID	GL-123250
Guideline Name	Xiaflex (collagenase clostridium histolyticum)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Xiaflex (collagenase clostridium histolyticum)
Dupuytren's Contracture Indicated for the treatment of adult patients with Dupuytren's contracture with a palpable cord. **Peyronie's Disease** Indicated for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy.

2 . 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

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

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)

AND **5** - Patient has a new plaque that results in a curvature deformity

3 . Endnotes

A. 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]
B. 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]
C. 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]

4 . References

1. Xiaflex Prescribing Information. Endo Pharmaceuticals, Inc. Malvern, PA. July 2022.

5 . Revision History

Date	Notes
3/28/2023	2023 Annual Review. No criteria changes. Updated references

Xolair (omalizumab)

Prior Authorization Guideline

Guideline ID	GL-134293
Guideline Name	Xolair (omalizumab)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/14/2003
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/18/2021 ; 03/17/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Xolair (omalizumab)
Allergic Asthma Indicated for adults and pediatric 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. 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. **Chronic Spontaneous Urticaria (CSU)** Indicated for the treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment. Limitations of Use: Xolair is not indicated for treatment of other forms of urticaria. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** Indicated for 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.

2 . Criteria

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	6 months [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to severe persistent allergic asthma [1, 2]

AND

2 - Positive skin test or in vitro reactivity to a perennial aeroallergen [1, D]

AND

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

3.1 Both of the following:

- Patient is 12 years of age or older
- Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL

OR

3.2 Both of the following:

- Patient is 6 years to less than 12 years of age
- Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL

AND

4 - Patient is currently being treated with ONE of the following, unless there is a contraindication or intolerance to these medications: [3, A]

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 - Prescribed by or in consultation with one of the following: [G]

- Pulmonologist
- Allergist/Immunologist

Product Name: Xolair	
Diagnosis	Allergic Asthma
Approval Length	12 Months
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates 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	3 months [E]
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 - 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)

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	6 months [B]
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

AND

2 - Patient has experienced at least one of the following:

- 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

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) [8, 9]

AND

3 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

4 - 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

Approval Criteria

1 - Patient demonstrates 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])

AND

2 - Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) [H]

AND

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

- Allergist/Immunologist
- Otolaryngologist
- Pulmonologist

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 [3]

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. 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]
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. 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]

C. 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].
D. 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]
E. 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]
F. 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]
G. Referral to an asthma specialist for consultation or comanagement is recommended if Xolair is being considered. [2]
H. Other agents used for nasal polyps include intranasal corticosteroids and nasal saline.

5 . References

1. Xolair Prescribing Information. Genentech, Inc. South San Francisco, CA. March 2023.
2. 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.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention (2022 update). 2022 www.ginasthma.org. Accessed April 2023.
4. Per clinical consult with asthma specialist, January 6, 2011.
5. 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.
6. 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.
7. DRUGDEX System [Internet database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed March 11, 2021.

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.
9. 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.

6 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes t o clinical intent

Xtandi (enzalutamide)

Prior Authorization Guideline

Guideline ID	GL-128550
Guideline Name	Xtandi (enzalutamide)

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 04/21/2021 ; 04/20/2022 ; 05/18/2023 ; 07/19/2023 ; 8/17/2023

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). **Off Label Uses: HRR Gene-mutated mCRPC [3]** Indicated for the treatment of adult patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Talzenna (talazoparib).

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 - If HRR gene-mutated metastatic disease, medication will be taken in combination with Talzenna (talazoparib)

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

Product Name: Xtandi	
Diagnosis	Castration-resistant prostate cancer (CRPC), Castration-sensitive prostate cancer (mCSPC)
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. Xtandi prescribing information. Astellas Pharma Inc. Northbrook, IL. September 2022.
2. 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.
3. Agarwal, Neeraj, et al. “Talazoparib plus Enzalutamide in Men with First-Line Metastatic Castration-Resistant Prostate Cancer (TALAPRO-2): A Randomised, Placebo-Controlled, Phase 3 Trial.” The Lancet, 4 June 2023, https://doi.org/10.1016/s0140-6736(23)01055-3.

4 . Revision History

Date	Notes
7/28/2023	Addition of new indication for HRR gene-mutated metastatic castration-resistant prostate cancer

Yonsa (abiraterone acetate) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127625
Guideline Name	Yonsa (abiraterone acetate) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/18/2018
P&T Revision Date:	02/13/2020 ; 05/14/2020 ; 05/20/2021 ; 12/15/2021 ; 05/19/2022 ; 05/18/2023 ; 7/19/2023

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

AND

2 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

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

Product Name: Yonsa	
Diagnosis	Castration-Resistant Prostate Cancer (mCRPC)
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer

AND

2 - One of the following:

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

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

3 . References

1. Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. March 2022.
2. 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.

4 . Revision History

Date	Notes
7/5/2023	Removed specialist requirement

Zaltrap (ziv-aflibercept)

Prior Authorization Guideline

Guideline ID	GL-124383
Guideline Name	Zaltrap (ziv-aflibercept)

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	11/13/2012
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

Drug Name: Zaltrap (ziv-aflibercept)
Metastatic Colorectal Cancer (mCRC) Indicated in combination with 5-fluorouracil, leucovorin, irinotecan-(FOLFIRI) for the treatment of patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen.

2 . Criteria

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

Approval Criteria

1 - Diagnosis of metastatic colon and/or rectal cancer

AND

2 - Used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen

AND

3 - Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)] [1, 2]

AND

4 - Prescribed by or in consultation with an oncologist

Product Name: Zaltrap	
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. Zaltrap prescribing information. Sanofi-Aventis. Bridgewater, NJ. December 2020.
2. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium [internet database]. National Comprehensive Cancer Network, Inc.; 2020. Updated periodically. Available by subscription at: www.nccn.org. Accessed April 6, 2023.

4 . Revision History

Date	Notes
5/3/2023	Annual review - updated reauth criteria to add "while on therapy" for clarification. Updated background and references.

Zelboraf (vemurafenib)

Prior Authorization Guideline

Guideline ID	GL-126934
Guideline Name	Zelboraf (vemurafenib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	2/21/2012
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 7/19/2023

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)

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)

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

A. 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

1. Zelboraf Prescribing Information. Genentech USA, Inc., May 2020.
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.

5 . Revision History

Date	Notes
7/18/2023	Removed Oncology specialist requirement

Zepatier (elbasvir/grazoprevir)

Prior Authorization Guideline

Guideline ID	GL-125945
Guideline Name	Zepatier (elbasvir/grazoprevir)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	11/18/2015
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 02/17/2022 ; 06/15/2022 ; 6/21/2023

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

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 is treatment-naive

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: 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

A. 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]
B. 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

1. Zepatier Prescribing Information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. December 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.

5 . Revision History

Date	Notes
6/6/2023	Annual review - no criteria changes; background updates

Zokinvy (lonafarnib)

Prior Authorization Guideline

Guideline ID	GL-118466
Guideline Name	Zokinvy (lonafarnib)

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/18/2021
P&T Revision Date:	02/18/2021 ; 02/17/2022 ; 2/16/2023

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 m^2 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. **Processing-Deficient Progeroid Laminopathies** Indicated in patients 12 months of age and older with a body surface area (BSA) of 0.39 m^2 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

Approval Criteria

1 - One of the following:

1.1 Diagnosis of Hutchinson-Gilford Progeria Syndrome

OR

1.2 For treatment of processing-deficient Progeroid Laminopathies with one of the following:

- Heterozygous LMNA mutation with progerin-like protein accumulation
- Homozygous or compound heterozygous ZMPSTE24 mutations

AND

2 - Patient is 12 months of age or older

AND

3 - Patient has a body surface area of 0.39 m^2 and above

3 . References

1. Zokinvy Prescribing Information. Eiger BioPharmaceuticals, Inc. Palo Alto, CA. November 2020.

4 . Revision History

Date	Notes
2/17/2023	Annual review - no criteria changes.

Zolinza (vorinostat)

Prior Authorization Guideline

Guideline ID	GL-131392
Guideline Name	Zolinza (vorinostat)

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	2/20/2007
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 09/21/2022 ; 07/19/2023 ; 9/20/2023

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]

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 therapy

3 . Endnotes

A. Examples of systemic therapies include (but are not limited to): [2] • Adcetris (brentuximab vedotin) • Cytoxan (cyclophosphamide) • Doxil (pegylated doxorubicin) • Extracorporeal photochemotherapy • Folotyn (pralatrexate) • Gemzar (gemcitabine) • Interferon-alpha • Leukeran (chlorambucil) • Nipent (pentostatin) • Poteligeo (mogamulizumab) • Targretin (bexarotene) • Temodar (temozolamide) • Toposar (etoposide) • Trexall (methotrexate) • Velcade (bortezomib)

4 . References

1. Zolinza Prescribing Information. Merck & Co, Inc. Whitehouse Station, NJ. January 2020.
2. National comprehensive cancer network (NCCN) clinical practice guidelines in oncology: Primary cutaneous lymphomas. v.1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf. Accessed September 9, 2021.

5 . Revision History

Date	Notes
8/23/2023	2023 Annual Review

Zydelig (idelalisib)

Prior Authorization Guideline

Guideline ID	GL-132842
Guideline Name	Zydelig (idelalisib)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	10/14/2014
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022 ; 07/19/2023 ; 10/18/2023

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 any patient, including patients with CLL, small lymphocytic lymphoma (SLL), follicular lymphoma (FL), and other indolent non-Hodgkin lymphomas. Zydelig is not indicated and is not recommended in combination with bendamustine and rituximab, or in combination with rituximab for the treatment of patients with FL, SLL, and other indolent non-Hodgkin lymphomas.

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.)

Notes	*This drug may require prior authorization.

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

1. Zydelig Prescribing Information. Gilead Sciences, Inc. Foster City, CA. February 2022.
2. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology. Chronic lymphocytic leukemia/small lymphocytic lymphoma. v.3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 2, 2022.

4 . Revision History

Date	Notes
9/11/2023	2023 Annual Review

Zykadia (ceritinib)

Prior Authorization Guideline

Guideline ID	GL-127126
Guideline Name	Zykadia (ceritinib)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/8/2014
P&T Revision Date:	06/17/2020 ; 02/18/2021 ; 06/16/2021 ; 05/19/2022 ; 05/18/2023 ; 7/19/2023

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)

AND

2 - One of the following: [2]

- Disease is metastatic
- Disease is recurrent

AND

3 - Tumor is anaplastic lymphoma kinase (ALK)-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 - 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

Product Name: Zykadia	
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. Zykadia Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2022.
2. The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 3, 2023.

4 . Revision History

Date	Notes
6/26/2023	Removed specialist requirement.

Zytiga (abiraterone acetate) - PA, NF

Prior Authorization Guideline

Guideline ID	GL-127847
Guideline Name	Zytiga (abiraterone acetate) - PA, NF

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/9/2013
P&T Revision Date:	02/13/2020 ; 02/18/2021 ; 03/17/2021 ; 11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 05/18/2023 ; 7/19/2023

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: 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 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to Xtandi (enzalutamide)

OR

2.2 For continuation of prior therapy

Product Name: Brand Zytiga	
Diagnosis	Castration-resistant prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration resistant (chemical or surgical) prostate cancer [2]

AND

2 - One of the following:

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

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: Generic abiraterone acetate	
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]

Product Name: 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 - One of the following:

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

- Xtandi (enzalutamide)

- Erleada (apalutamide)

OR

2.2 For continuation of prior therapy

Product Name: Brand Zytiga	
Diagnosis	Castration-sensitive prostate cancer
Approval Length	12 month(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of castration-sensitive prostate cancer

AND

2 - One of the following:

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

- Xtandi (enzalutamide)
- Erleada (apalutamide)

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: Generic abiraterone acetate	
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	

Product Name: Brand Zytiga, Generic abiraterone acetate	
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	

3 . References

1. Zytiga Prescribing Information. Janssen Biotech Inc. Horsham, PA. August 2021.
2. 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.

4 . Revision History

Date	Notes
7/11/2023	Removed specialist requirement