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5HT-1 Receptor Agonists (Triptans)



Prior Authorization Guideline

Guideline ID	GL-120629
Guideline Name	5HT-1 Receptor Agonists (Triptans)

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	2/13/1998
P&T Revision Date:	11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Zomig (zolmitriptan) nasal spray
Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

2 . Criteria

Product Name: Zomig nasal spray or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)

Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Both of the following:</p> <p>2.1.1 Patient is 12 to 17 years of age</p> <p style="text-align: center;">AND</p> <p>2.1.2 Trial and failure (of a minimum 30-day supply) or intolerance to rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)</p> <p style="text-align: center;">OR</p> <p>2.2 Both of the following:</p> <p>2.2.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>2.2.2 Trial and failure (of a minimum 30-day supply) or intolerance to two of the following generics [A, B]:</p> <ul style="list-style-type: none">• Almotriptan tablet• Eletriptan tablet• Frovatriptan tablet• Naratriptan tablet• Rizatriptan tablet/rizatriptan orally dissolving tablet (ODT)• Sumatriptan tablet/nasal spray• Zolmitriptan tablet/zolmitriptan ODT	

3 . Endnotes

- A. All triptans are FDA-approved for the acute treatment of migraines with or without aura in adults [1]. Those agents FDA-approved in pediatric patients include almotriptan, sumatriptan/naproxen, zolmitriptan nasal spray (for ≥12 years of age), and rizatriptan (for ≥6 years of age).
- B. Triptans are a well established, effective treatment option for There is limited head-to-head data available, acute migraine [2]. which makes it difficult to recommend the use of one agent over another [2].

4 . References

- 1. Drugs@FDA [internet database]. Rockville (MD): Food and Drug Administration (US), Center for Drug Evaluation and Research; Updated periodically. Available from: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>. Accessed January 27, 2023.
- 2. Schwedt TJ, Garza I. Acute treatment of migraine in adults. UpToDate. Available by subscription at: <http://www.uptodate.com/>. Accessed January 27, 2023.
- 3. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.

5 . Revision History

Date	Notes
3/2/2023	Annual review: Updated criteria and background.

Administrative Non-Formulary & Excluded Drug Exceptions Process



Prior Authorization Guideline

Guideline ID	GL-136777
Guideline Name	Administrative Non-Formulary & Excluded Drug Exceptions Process

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/19/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 01/20/2021 ; 03/17/2021 ; 05/20/2021 ; 06/16/2021 ; 11/18/2021 ; 08/18/2022 ; 11/17/2022 ; 09/20/2023 ; 11/16/2023 ; 12/13/2023

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs. This guideline will not apply to drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity **

1 . Criteria

Product Name: A Non-Preferred Non-Formulary or Excluded Medication*, ** (Brand Absorica, Absorica LD, Atopaderm, Azesco, Bensal HP, generic chlorzoxazone, Brand Diclofenac Epolamine, Brand Doryx, generic doxepin cream, Epiceram, generic fenoprofen calcium, Flector, Fluovix, Folic-K, Genicin Vita-S, Brand Inderal XL, Innopran XL, Kamdoy, Kelarx, Brand Lidocaine-tetracaine cream, Brand Naprosyn, generic naproxen-esomeprazole, Ortho DF, Brand Pennsaid, Pliaglis, Pregenna, Prodigen, Brand Prudoxin, Rayos, Relafen DS,

Sitavig, Sprix, Tivorbex, Tolsura, Brand Vimovo, Xerese, Xhance, Yosprala, Zipsor, Brand Zonalon, Zorvolex, ZT Lido, Brand Zyclara, Zylflo)	
Approval Length	6 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting request is for an FDA-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Paid claims or submission of medical records (e.g., chart notes) (document drug, duration, dose and date of use) documenting history of use of ALL available formulary alternative(s)* (if request is for a combination product, member must have documentation indicating concurrent use of separate agents)</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following:</p> <p>3.1 Documentation provided stating the formulary alternative(s)* has/have not been effective</p> <p style="text-align: center;">AND</p> <p>3.2 Justification/rationale provided explaining how the Non-Formulary or Excluded Medication is expected to provide benefit when the formulary alternative* product(s) has/have not been shown to be effective despite having the same active ingredient and/or same mechanism of action</p>	
Notes	*See table in background section for a list of the Non-Formulary or Excluded Medications and their preferred formulary alternatives. Please double check plan formulary for coverage. For off-label use, do not review against the off-label administration guideline. Deny per guideline criteria. **For off-label use, do not review against the off-label administration guideline. Deny per guideline criteria.

Product Name: A non-formulary or excluded* contraceptive drug

Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <ul style="list-style-type: none"> • Patient is using the requested product for contraception or other FDA-approved condition** • The requested product is medically necessary*** <p style="text-align: center;">OR</p> <p>1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met</p>	
Notes	<p>*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. **Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg , amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner’s syndrome; (17) Uterine fibroids or adenomyosis. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.</p>

Product Name: A non-formulary or excluded* drug	
Approval Length	6 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Both of the following:</p>	

1.1 One of the following:

1.1.1 If the requested drug has a formulary alternative with the same active ingredient, both of the following:

1.1.1.1 Submission of medical records (e.g., chart notes) documenting the patient has experienced intolerance (e.g., allergy to excipient) with a formulary alternative that has the same active ingredient

AND

1.1.1.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives within the same therapeutic class. If only 1 formulary alternative within the therapeutic class is available, the patient must have tried the formulary alternative within the therapeutic class AND 1 additional formulary alternative. If there are no formulary alternatives within the same therapeutic class, the patient must have failed or had contraindication or intolerance to 2 formulary alternatives.

OR

1.1.2 If the requested drug is a fixed-dose combination product with each individual ingredients available on formulary, both of the following:

1.1.2.1 Submission of medical records (e.g., chart notes) documenting the patient has experienced intolerance (e.g., allergy to excipient) with the individual ingredients in the combination product

AND

1.1.2.2 Submission of medical records (e.g., chart notes) or paid claims documenting the patient has tried and failed at least 2 additional formulary alternatives

OR

1.1.3 If only over-the-counter (OTC) equivalents are available, patient has tried and failed or has contraindications or intolerance to 3 OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial]

OR

1.1.4 If formulary alternatives are available and do not meet above scenarios, submission of medical records (e.g., chart notes) or paid claims documenting patient has tried and failed, or has contraindication or intolerance to at least three formulary alternatives. If only one or only two alternatives are available, the patient must have failed or had contraindications or intolerance to all available formulary alternatives

OR

1.1.5 No formulary alternative or OTC equivalent is appropriate to treat the patient's condition

AND

1.2 One of the following:

1.2.1 Both of the following:

1.2.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Notes	*Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity. *For Premium Drug Exclusion on Premium formulary, if the target drug is listed on the PREMVDL grid, the patient must try and fail, or have specific medical reason(s) for why the number of alternatives specified by the grid is not appropriate.
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2 . Background

Benefit/Coverage/Program Information	
Non-Formulary or Excluded Medications and their *Formulary Alternatives	
Non-Formulary or Excluded Medication	*Formulary Alternatives
Brand Absorica, Absorica LD	Amnesteem Claravis Isotretinoin Myorisan Zenatane
Atopaderm	Desonide Hydrocortisone
Azesco	PrePLUS prenatal vitamin
Bensal HP	Podofilox Ciclopirox
Generic chlorzoxazone	Methocarbamol Cyclobenzaprine tablet Metaxalone Orphenadrine ER Tizanidine
Generic doxepin 5% cream, Brand Prudoxin, Brand Zonalon	Betamethasone dipropionate cream Tacrolimus 0.1% ointment
Brand Doryx	Generic doxycycline delayed release Generic doxycycline monohydrate Brand Vibramycin
Epiceram	OTC topical moisturizer (e.g., Aquaphor)

Generic fenoprofen calcium, Brand Naprosyn	Celecoxib Ibuprofen (tablet/suspension) Diclofenac Etodolac Meloxicam
Flector, Brand Diclofenac epolamine	Celecoxib Ibuprofen Diclofenac (oral) Etodolac Meloxicam
Fluovix	Fluocinonide cream 0.1%
Folic-K, Genicin Vita-S	Generic B-Complex with C and Folic Acid
Inderal XL/Innopran XL	Propranolol extended release Nadolol Pindolol Timolol maleate tablets
Kamdoy	OTC Lidocaine
Kelarx	Scaraway (OTC)
Brand Lidocaine-tetracaine cream, Pliaglis	Lidocaine-prilocaine cream Lidocaine cream
Ortho DF	Vitamin D3 (OTC) Folic Acid
Pennsaid	Diclofenac sodium solution 1.5% Diclofenac sodium solution 2%
Pregenna	Atabex OB Tab 29-1mg
Prodigen	Visbiome
Relafen DS, Zipsor, Zorvolex	Diclofenac Etodolac

	Ketoprofen Naproxen Meloxicam Nabumetone Piroxicam Sulindac	
Rayos	Methylprednisolone Prednisolone Prednisone	
Sitavig	Acyclovir 5% cream Penciclovir 1% cream Acyclovir oral Valacyclovir oral	
Sprix	Brand Ketorolac nasal spray Generc ketorolac oral tablets	
Tivorbex	Celecoxib Ibuprofen (tablet/suspension) Indomethacin Colcrys Diclofenac Etodolac Meloxicam	
Tolsura	Itraconazole 100 mg capsule (higher strength)	
Brand Vimovo, generic naproxen/esomeprazole	NSAID	ANTI-ULCER AGENT
	Diclofenac	Esomeprazole
	Indomethacin	Lansoprazole
	Ketoprofen	Omeprazole

	Naproxen	Omeprazole/Sodium bicarbonate
	Meloxicam	Pantoprazole
	Nabumetone	Rabeprazole
	Piroxicam	
	Sulindac	
Xerese	Acyclovir 5% Cream Hydrocortisone 1% Cream	
Xhance	Generic mometasone Beconase AQ	
Yosprala	Aspirin	Omeprazole
ZTlido	Lidocaine 5% patch Gabapentin Pregabalin	
Brand Zyclara	Imiquimod 5% Fluorouracil	
Zyflo	Montelukast Zafirlukast	

3 . Revision History

Date	Notes
11/27/2023	Updated Non-Formulary or Excluded drug criteria to reorder criteria. No changes to clinical intent. Removed Auvi-Q as target drug.

Afrezza (insulin human, inhalation powder) - PA, NF



Prior Authorization Guideline

Guideline ID	GL-133014
Guideline Name	Afrezza (insulin human, inhalation powder) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/20/2014
P&T Revision Date:	02/13/2020 ; 02/13/2020 ; 02/18/2021 ; 05/20/2021 ; 02/17/2022 ; 02/16/2023

1 . Indications

Drug Name: Afrezza (insulin human, inhalation powder)
Diabetes Mellitus Indicated to improve glycemic control in adult patients with diabetes mellitus. Limitations of Use: Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus. Afrezza is not recommended for the treatment of diabetic ketoacidosis. The safety and efficacy of Afrezza in patients who smoke has not been established. The use of Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

2 . Criteria

Product Name: Afrezza	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of type 1 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)</p> <p style="text-align: center;">OR</p> <p>1.2 Diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>2 - Unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]</p> <ul style="list-style-type: none">• Physical impairment• Visual impairment• Lipohypertrophy <p style="text-align: center;">AND</p> <p>3 - Documented FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an endocrinologist</p>	

AND

5 - Afrezza will NOT be approved in patients:

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

Product Name: Afrezza	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Repeat pulmonary function test confirms that the patient has NOT experienced a decline of 20% or more in FEV1 from baseline [1]</p> <p style="text-align: center;">AND</p> <p>2 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>3 - Both of the following: [1]</p> <ul style="list-style-type: none"> • Patient does NOT have chronic lung disease (e.g., asthma, chronic obstructive pulmonary disease [COPD]) • Patient does not smoke cigarettes 	

Product Name: Afrezza	
Approval Length	6 month(s)

Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of type 1 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>1.1.2 Used in combination with a long-acting insulin (e.g., Lantus, Levemir)</p> <p style="text-align: center;">OR</p> <p>1.2 Diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) documenting that patient is unable to self-inject short-acting insulin multiple times daily due to one of the following: [4]</p> <ul style="list-style-type: none">• Physical impairment• Visual impairment• Lipohypertrophy <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) documenting FEV1 within the last 60 days greater than or equal to 70% of expected normal as determined by the physician [A]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an endocrinologist</p>	

AND

5 - Afrezza will NOT be approved in patients:

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

3 . Endnotes

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

4 . References

1. Afrezza Prescribing Information. MannKind Corporation. Danbury, CT. February 2020.
2. Bode BW, McGill JB, Lorber DL, et al. Inhaled Technosphere Insulin Compared With Injected Prandial Insulin in Type 1 Diabetes: A Randomized 24-Week Trial. Diabetes Care. 2015 Dec;38(12):2266-73.
3. Rosenstock J, Franco D, Korpachev V, et al. Inhaled Technosphere Insulin Versus Inhaled Technosphere Placebo in Insulin-Naïve Subjects With Type 2 Diabetes Inadequately Controlled on Oral Antidiabetes Agents. Diabetes Care. 2015 Dec;38(12):2274-81.
4. Per clinical consult with endocrinologist, August 6, 2014.

5 . Revision History

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

Anti-Parkinson’s Agents



Prior Authorization Guideline

Guideline ID	GL-132619
Guideline Name	Anti-Parkinson’s Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/22/1998
P&T Revision Date:	03/18/2020 ; 06/17/2020 ; 03/17/2021 ; 04/21/2021 ; 01/19/2022 ; 03/16/2022 ; 03/15/2023 ; 05/18/2023

1 . Indications

Drug Name: Rytary (carbidopa and levodopa) extended-release capsules
Parkinson’s disease Indicated for the treatment of Parkinson’s disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication
Drug Name: Duopa (carbidopa and levodopa) enteral suspension
Advanced Parkinson’s disease Indicated for the treatment of motor fluctuations in patients with advanced Parkinson’s disease.
Drug Name: Xadago (safinamide) tablets
Parkinson’s disease Indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease experiencing "off" episodes.
Drug Name: Gocovri (amantadine) extended-release capsules

Dyskinesia in Parkinson's disease Indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

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

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

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

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

Drug Name: Dhivy (carbidopa-levodopa)

Parkinson's Disease Indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication.

2 . Criteria

Product Name: Rytary	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply) of ONE of the following:</p> <ul style="list-style-type: none"> • Generic carbidopa-levodopa immediate release • Generic carbidopa-levodopa extended release 	

Product Name: Xadago	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply) of BOTH of the following:</p> <ul style="list-style-type: none"> • rasagiline mesylate • selegiline 	

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Parkinson's disease</p> <p style="text-align: center;">AND</p> <p>2 - Patient is levodopa-responsive [A, B]</p> <p style="text-align: center;">AND</p> <p>3 - Patient experiences disabling "Off" periods for a minimum of 3 hours/day [B]</p>	

AND

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

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

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Duopa	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Patient demonstrates positive clinical response to therapy	

Product Name: Gocovri	
Diagnosis	Dyskinesia in Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of Parkinson's disease	

AND
2 - Patient is experiencing dyskinesia
AND
3 - Patient is receiving concurrent levodopa-based therapy [5, D]
AND
4 - Trial and failure or intolerance to amantadine immediate release
AND
5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	"Off" Episodes in Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Parkinson's disease</p> <p style="text-align: center;">AND</p> <p>2 - Patient is experiencing "off" episodes [E, 6]</p>	

AND

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

AND

4 - Both of the following:

4.1 Trial and failure, or intolerance to amantadine immediate release

AND

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

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

AND

5 - Prescribed by or in consultation with a neurologist

Product Name: Gocovri	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., decreased "off" periods, decreased "on" time with troublesome dyskinesia) [D]</p>	

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Parkinson's disease</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication or intolerance to BOTH of the following:</p> <p> 2.1 amantadine immediate release</p> <p style="text-align: center;">AND</p> <p> 2.2 ONE of the following: [9]</p> <ul style="list-style-type: none"> • carbidopa-levodopa • MAO-B Inhibitor (e.g., rasagiline, selegiline) • Dopamine Agonist (e.g., pramipexole, ropinirole) <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a neurologist</p>	

Product Name: Osmolex ER	
Diagnosis	Drug-Induced Extrapramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient is experiencing drug-induced extrapyramidal reactions

AND

2 - One of the following: [10]

2.1 Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication

OR

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

AND

3 - Trial and failure or intolerance to amantadine immediate release

AND

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

- Neurologist
- Psychiatrist

Product Name: Osmolex ER	
Diagnosis	Parkinson's Disease, Drug-Induced Extrapyramidal Reactions
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy

Product Name: Dhivy

Approval Length	12 month(s)
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Guideline Type	Step Therapy
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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) of both of the following:

- Generic carbidopa-levodopa immediate release (IR)
- Generic carbidopa-levodopa oral disintegrating tablet (ODT)

3 . Endnotes

- A. The efficacy of Duopa was established in a randomized, double-blind, double-dummy, active controlled, parallel group, 12-week study in patients with advanced Parkinson's disease who were levodopa-responsive and had persistent motor fluctuations while on treatment with oral immediate-release carbidopa-levodopa and other Parkinson's disease medications. [2, 3]
- B. Patients were eligible for participation in the studies if they were experiencing 3 hours or more of "Off" time on their current Parkinson's disease drug treatment and they demonstrated a clear responsiveness to treatment with levodopa. [2, 3]
- C. Most patients (89%) were taking at least one concomitant medication for Parkinson's disease (e.g., dopaminergic agonist, COMT-inhibitor, MAO B inhibitor) in addition to oral immediate-release carbidopa-levodopa. [2, 3]
- D. The efficacy of Gocovri was established in two Phase III randomized, double-blind, placebo-controlled trials, a 12 week and 24 week study in patients with Parkinson's disease were treated with levodopa. Both studies demonstrate statistically significant

and clinically relevant reduction in dyskinesia compared to placebo. Also, both studies showed that Gocovri-treated patients experienced an increase in functional time daily (defined as ON time without troublesome dyskinesia) compared to placebo-treated patients. [6, 7]

- E. "Off" time is defined as the amount of time the Parkinson's Disease medication was not controlling motor symptoms. [6]

4 . References

1. Duopa Prescribing Information. AbbVie Inc. North Chicago, IL. December 2019.
2. Olanow CW, Kieburtz K, Odin P, et al. Continuous intrajejunal infusion of levodopa-carbidopa intestinal gel for patients with advanced Parkinson's disease: a randomised, controlled, double-blind, double-dummy study. *Lancet Neurol.* 2014 Feb;13(2):141-9.
3. Rytary Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2019.
4. Xadago Prescribing Information. US WorldMeds, LLC. Louisville, KY. August 2021.
5. Gocovri Prescribing Information. Adamas Pharma, LLC. Emeryville, CA. January 2021.
6. Pahwa R, Tanner CM, Hauser RA, et al. ADS-5102 (Amantadine) Extended- Release Capsules for Levodopa-Induced Dyskinesia in Parkinson Disease (EASE LID Study): A Randomized Clinical Trial. *JAMA Neurol.* 2017 Aug;1;74(8): 941-949.
7. Pahwa R, Tanner CM, Hauser Ra, et al. Amantadine Extended Release for Levodopa-Induced Dyskinesia in Parkinson's Disease (EASED Study). *Mov Disorder.* 2015 May; 30(6):788-95.
8. Osmolex ER Prescribing Information. Vertical Pharmaceuticals, LLC. Bridgewater, NJ. March 2021.
9. National Institute of Health and Clinical Excellence (NICE). Parkinson's disease in adults. NICE guideline [NG71]. July 2017. Available at: <https://www.nice.org.uk/guidance/ng71/chapter/Recommendations>. Accessed January 28, 2021.
10. Muench J, Hamer AM. Adverse effects of antipsychotic medications. *Am Fam Physician.* 2010 Mar 1;81(5):617-622.
11. Oertel W, Eggert K, Pahwa R, et al. Randomized, placebo-controlled trial of ADS-5102 (amantadine) extended-release capsules for levodopa-induced dyskinesia in Parkinson's disease (EASE LID 3). *Mov Disord.* 2017;32(12):1701-1709.
12. Dhivy Prescribing Information. Riverside Pharmaceuticals Corporation. Washington, DC. November 2021.

5 . Revision History

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

Anticonvulsants

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Prior Authorization Guideline

Guideline ID	GL-121749
Guideline Name	Anticonvulsants

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/19/1999
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 10/20/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Briviact (brivaracetam)
Partial-Onset Seizures Indicated for the treatment of partial-onset seizures in patients 1 month of age and older.

2 . Criteria

Product Name: Briviact tablet, oral solution	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - One of the following:

1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

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

- lamotrigine immediate-release (IR)
- levetiracetam IR
- levetiracetam extended-release (ER)
- oxcarbazepine IR
- topiramate IR

OR

2 - For continuation of prior therapy

3 . References

1. Briviact Prescribing Information. UCB, Inc. Smyrna, GA. September 2021.

4 . Revision History

Date	Notes
2/27/2023	Annual Review - no criteria changes

Antidepressants

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Prior Authorization Guideline

Guideline ID	GL-121765
Guideline Name	Antidepressants

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	9/28/1998
P&T Revision Date:	03/20/2019 ; 03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Trintellix (vortioxetine)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults.
Drug Name: Fetzima (levomilnacipran extended-release)
Major Depressive Disorder Indicated for the treatment of major depressive disorder (MDD) in adults. Limitation of Use: Fetzima is not approved for the management of fibromyalgia. The efficacy and safety of Fetzima for the management of fibromyalgia have not been established.
Drug Name: Emsam (selegiline patch)
Major Depressive Disorder Indicated for the treatment of adults with major depressive disorder (MDD)

2 . Criteria

Product Name: Fetzima or Fetzima Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>1.2 Trial and failure, contraindication, or intolerance to any two of the following generics:</p> <ul style="list-style-type: none"> • desvenlafaxine succinate extended-release (ER) • duloxetine • venlafaxine or venlafaxine ER <p style="text-align: center;">OR</p> <p>2 - For continuation of prior therapy</p>	

Product Name: Trintellix, Emsam	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p>	

AND

1.2 Trial and failure, contraindication, or intolerance to any two of the following generics:

- bupropion
- citalopram
- desvenlafaxine succinate extended-release (ER)
- duloxetine
- escitalopram
- fluoxetine
- mirtazapine
- paroxetine or paroxetine ER
- sertraline
- venlafaxine or venlafaxine ER

OR

2 - For continuation of prior therapy

3 . References

1. Emsam Prescribing Information. Somers et Pharmaceuticals, Inc. Morgantown, WV. July 2017.
2. American Psychiatric Association. Practice guideline for the treatment of patients with major depressive disorder, third edition. Oct. 2010.
http://psychiatryonline.org/pb/assets/raw/sitewide/practice_guidelines/guidelines/mdd.pdf
. Accessed January 21, 2022.
3. Soleimani L, Lapidus KA, Losifescu DV. Diagnosis and treatment of major depressive disorder. *Neurol Clin.* 2011;29(1):177-93.
4. American Geriatrics Society. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults. *J Am Geriatr Soc.* 2015;63:2227-46.
5. Trintellix Prescribing Information. Takeda Pharmaceuticals America, Inc. Lexington, MA. September 2021.
6. Fetzima Prescribing Information. Allergan USA, Inc. Madison, NJ. September 2021.

4 . Revision History

Date	Notes
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2/28/2023	Annual Review - removal of Aplenzin and Paxil oral solution. Addition of Emsam
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Antiemetics Quantity Limit Overrides

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Prior Authorization Guideline

Guideline ID	GL-134125
Guideline Name	Antiemetics Quantity Limit Overrides

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	05/14/2020 ; 08/13/2020 ; 10/20/2021 ; 10/19/2022 ; 10/18/2023

1 . Indications

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

Postoperative nausea and vomiting Used orally for the prevention of postoperative nausea and vomiting. [13]

Drug Name: Emend (aprepitant)

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

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

Drug Name: Granisetron

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

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

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

Drug Name: Marinol (dronabinol)

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

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

Drug Name: Sancuso (granisetron transdermal system)

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

Drug Name: Sustol (granisetron injection)
Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.
Drug Name: Varubi (rolapitant)
Chemotherapy-induced nausea and vomiting Indicated in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.
Drug Name: Zofran (ondansetron), Zuplenz (ondansetron oral soluble film)
Chemotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m ² . Also indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.
Radiotherapy-induced nausea and vomiting Indicated for the prevention of nausea and vomiting associated with radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
Postoperative nausea and vomiting Indicated for the prevention of postoperative nausea and/or vomiting. As with other antiemetics, routine prophylaxis is not recommended for patients in whom there is little expectation that nausea and/or vomiting will occur postoperatively. In patients where nausea and/or vomiting must be avoided postoperatively, Zofran Tablets, Zofran ODT Orally Disintegrating Tablets, Zofran Oral Solution, and Zuplenz are recommended even where the incidence of postoperative nausea and/or vomiting is low.
Off Label Uses: Hyperemesis gravidarum Used in the management of hyperemesis gravidarum. [10, 16]

2 . Criteria

Product Name: Akynzeo, Anzemet, Generic dronabinol, Brand Emend, Generic aprepitant, granisetron, Brand Marinol, Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, Sancuso, Sustol, Varubi, or Zuplenz	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Patient is receiving moderately to highly emetogenic chemotherapy

AND

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

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

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

Approval Criteria

1 - Diagnosis of radiotherapy-induced nausea and vomiting

AND

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

AND

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

Product Name: Generic ondansetron 24 mg tablet, Generic ondansetron oral solution, Generic ondansetron ODT, or Zuplenz	
Diagnosis	Hyperemesis gravidarum
Approval Length	6 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Diagnosis of nausea and vomiting due to pregnancy (i.e., hyperemesis gravidarum) [10, 16]</p> <p style="text-align: center;">AND</p> <p>2 - History of failure, contraindication, or intolerance to at least one of the following: [A]</p> <ul style="list-style-type: none"> • doxylamine • metoclopramide (Reglan) • prochlorperazine (Compazine) • promethazine (Phenergan) • pyridoxine (Vitamin B6) <p style="text-align: center;">AND</p> <p>3 - Patient has had at least a partial response to therapy at a dose within the quantity limit</p>	

3 . Background

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

4 . Endnotes

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

5 . References

1. Akynzeo prescribing information. Helsinn Therapeutics (U.S.), Inc. Iselin, NJ. February 2023.
2. Anzemet prescribing information. Validus Pharmaceuticals LLC. Parsippany, NJ. September 2021.
3. Emend prescribing information. Merck Sharp & Dohme Corp. Whitehouse Station, NJ. May 2022.
4. Granisetron prescribing information. Ascend Laboratories. Montvale, NJ. July 2022.
5. Marinol prescribing information. AbbVie Inc. North Chicago, IL. August 2017.
6. Sancuso prescribing information. Kyowa Kirin, Inc. Bedminster, NJ. December 2022.
7. Varubi prescribing information. TerSera Therapeutics LLC. Deerfield, IL. August 2020.
8. Zofran prescribing information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. June 2020.
9. Zuplenz prescribing information. Fortovia Therapeutics, Inc. Raleigh, NC. May 2020.
10. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Reuters (Healthcare) Inc.; Updated periodically. Available by subscription at: <http://www.thomsonhc.com/>. Accessed September 9, 2021.
11. Fauser AA, Russ W, Bischoff M. Oral dolasetron mesilate (MDL 73,147EF) for the control of emesis during fractionated total-body irradiation and high-dose cyclophosphamide in patients undergoing allogeneic bone marrow transplantation. *Support Care Cancer*. 1997 May;5(3):219-22.
12. Basch E, Prestrud AA, Hesketh PJ, et al. Antiemetics: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2011;29(31):4189-98.
13. AHFS Drug Information website. Available at: <https://online.lexi.com/lco/action/doc/retrieve/docid/250/413041>. Accessed September 9, 2021.

14. Fujii Y, Tanaka H, Kawasaki T. Preoperative oral granisetron for the prevention of postoperative nausea and vomiting after breast surgery. *Eur J Surg.* 2001 Mar;167(3):184-7.
15. Fujii Y, Tanaka H, Kawasaki T. Prophylaxis with oral granisetron for the prevention of nausea and vomiting after laparoscopic cholecystectomy: a prospective randomized study. *Arch Surg.* 2001 Jan;136(1):101-4.
16. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2018; 103(1):15-30.
17. Sustol prescribing information. Heron Therapeutics. San Diego, CA. May 2023.

6 . Revision History

Date	Notes
10/2/2023	Annual review: No criteria changes. Removed Brand Zofran oral solution from guideline as it is obsolete. Updated references.

Antigout Agents



Prior Authorization Guideline

Guideline ID	GL-129248
Guideline Name	Antigout Agents

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	9/28/2016
P&T Revision Date:	10/17/2018 ; 10/16/2019 ; 10/21/2020 ; 12/01/2021 ; 08/18/2022 ; 8/17/2023

1 . Indications

Drug Name: Uloric (febuxostat)
Gout A xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable. Uloric is not recommended for the treatment of asymptomatic hyperuricemia.

2 . Criteria

Product Name: generic febuxostat	
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, contraindication, or intolerance to allopurinol

3 . References

1. Uloric Prescribing Information. Takeda Pharmaceuticals America, Inc. Deerfield, IL. April 2023.

4 . Revision History

Date	Notes
8/2/2023	Annual review, no changes to criteria

Antimalarial Agents



Prior Authorization Guideline

Guideline ID	GL-124353
Guideline Name	Antimalarial Agents

Guideline Note:

Effective Date:	7/1/2023
P&T Approval Date:	8/24/2001
P&T Revision Date:	02/13/2020 ; 06/17/2020 ; 07/21/2021 ; 05/19/2022 ; 5/18/2023

1 . Indications

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

2 . Criteria

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

Approval Criteria	
1 - Requests for coverage when used solely for the treatment or prevention of nocturnal leg cramps are not authorized and will not be approved [1, C]	
Notes	*Nocturnal leg cramp is an off-label use.

Product Name: Brand Qualaquin, Generic quinine sulfate	
Diagnosis	Malaria
Approval Length	7 days [1]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of uncomplicated malaria</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Both of the following:</p> <p>2.1.1 Treatment in areas of chloroquine-sensitive malaria [2-4, A]*</p> <p style="text-align: center;">AND</p> <p>2.1.2 Trial and failure, contraindication or intolerance to one of the following:</p> <ul style="list-style-type: none"> • chloroquine • hydroxychloroquine <p style="text-align: center;">OR</p> <p>2.2 Treatment in areas of chloroquine-resistant malaria [2-4, B]*</p>	

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

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

4 . References

1. Qaliquin Prescribing Information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ. August 2019.
2. Center for Disease Control Traveler's Health - Yellow Book 2020 edition. Chapter 4: Infectious diseases related to travel - malaria. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/malaria>. Accessed April 6, 2023.
3. Center for Disease Control. Guideline for treatment of malaria in the United States. Available at: http://www.cdc.gov/malaria/diagnosis_treatment/treatment.html. Accessed April 6, 2023.
4. Griffith KS, Lewis LS, Mali S, Parise ME. Treatment of malaria in the United States. A systematic review. JAMA. 2007;297(20):2264-77.

5 . Revision History

Date	Notes
5/3/2023	Annual review - updated references.

Atypical Antipsychotics



Prior Authorization Guideline

Guideline ID	GL-121774
Guideline Name	Atypical Antipsychotics

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/22/1998
P&T Revision Date:	03/18/2020 ; 10/21/2020 ; 02/18/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Fanapt (iloperidone)
<p>Schizophrenia Indicated for the treatment of adults with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia.</p>

2 . Criteria

Product Name: Fanapt or Fanapt Titration Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>1.2 Trial and failure (to a minimum 30 day supply), contraindication, or intolerance to two of the following:</p> <ul style="list-style-type: none"> • aripiprazole • olanzapine • quetiapine IR/ER • risperidone • clozapine • ziprasidone • paliperidone • asenapine <p style="text-align: center;">OR</p> <p>2 - For continuation of prior therapy</p>	

3 . Background

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

4 . References

1. Fanapt prescribing information. Vanda Pharmaceuticals Inc. Washington, D.C. January 2016.

5 . Revision History

Date	Notes
2/27/2023	Annual review - no criteria change

Atypical Antipsychotics - PA, ST



Prior Authorization Guideline

Guideline ID	GL-137131
Guideline Name	Atypical Antipsychotics - PA, ST

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/22/1998
P&T Revision Date:	02/13/2020 ; 03/18/2020 ; 10/21/2020 ; 02/18/2021 ; 11/18/2021 ; 02/17/2022 ; 09/21/2022 ; 11/17/2022 ; 02/16/2023 ; 12/13/2023

1 . Indications

Drug Name: Fanapt (iloperidone)
Schizophrenia Indicated for the treatment of adults with schizophrenia. When deciding among the alternative treatments available for this condition, the prescriber should consider the finding that Fanapt is associated with prolongation of the QTc interval. Prolongation of the QTc interval is associated in some other drugs with the ability to cause torsade de pointes-type arrhythmia, a potentially fatal polymorphic ventricular tachycardia which can result in sudden death. In many cases this would lead to the conclusion that other drugs should be tried first. Whether Fanapt will cause torsade de pointes or increase the rate of sudden death is not yet known. Patients must be titrated to an effective dose of Fanapt. Thus, control of symptoms may be delayed during the first 1 to 2 weeks of treatment compared to some other antipsychotic drugs that do not require a similar titration. Prescribers should be mindful of this delay when selecting an antipsychotic drug for the treatment of schizophrenia.
Drug Name: Nuplazid (pimavanserin)
Parkinson's disease psychosis Indicated for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Drug Name: Secuado (asenapine)
Schizophrenia Indicated for the treatment of adults with schizophrenia
Drug Name: Caplyta
Schizophrenia Indicated for the treatment of schizophrenia in adults
Bipolar Depression Indicated for the treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate
Drug Name: Lybalvi
Schizophrenia Indicated for the treatment of schizophrenia in adults
Bipolar I disorder Indicated for the acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate in adults with Bipolar I disorder. Indicated as maintenance monotherapy treatment in adults with Bipolar I disorder.
Drug Name: Saphris
Schizophrenia Indicated for the treatment of schizophrenia in adults
Bipolar I Disorder Indicated for acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age, indicated for adjunctive treatment to lithium or valproate in adults, and indicated for maintenance monotherapy treatment in adults
Drug Name: Invega Hafyera
Schizophrenia Indicated for the treatment of schizophrenia in adults after they have been adequately treated with either a once-a-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA SUSTENNA) for at least four months, or an every-three-month paliperidone palmitate extended-release injectable suspension (e.g., INVEGA TRINZA) for at least one three-month cycle.

2 . Criteria

Product Name: Nuplazid	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Parkinson's disease

AND

1.2 Patient has at least one of the following:

- Hallucinations
- Delusions

OR

2 - For continuation of prior therapy

Product Name: Fanapt, Fanapt Pak, Secuado, Brand Saphris, Lybalvi	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p>AND</p> <p>1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:</p> <ul style="list-style-type: none">• aripiprazole• olanzapine• quetiapine IR/ER• risperidone• clozapine	

<ul style="list-style-type: none"> • ziprasidone • paliperidone • asenapine <p style="text-align: center;">OR</p> <p>2 - For continuation of prior therapy</p>

Product Name: Invega Hafyera	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p style="padding-left: 20px;">1.1 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>1.2 Trial of one of the following:</p> <ul style="list-style-type: none"> • Invega Sustenna for at least 4 months • Invega Trinza for at least one 3-month cycle <p style="text-align: center;">OR</p> <p>2 - For continuation of prior therapy</p>	

Product Name: Caplyta	
Approval Length	12 month(s)
Guideline Type	Step Therapy

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of Schizophrenia

AND

1.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:

- aripiprazole
- olanzapine
- quetiapine IR/ER
- risperidone
- clozapine
- ziprasidone
- paliperidone
- asenapine

OR

2 - BOTH of the following:

2.1 Patient has a diagnosis of Bipolar Depression

AND

2.2 Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to quetiapine IR/ER

OR

3 - For continuation of prior therapy

3 . References

1. Fanapt prescribing information. Vanda Pharmaceuticals, Inc. Washington, D.C. January 2016.
2. Nuplazid prescribing information. Acadia Pharmaceuticals Inc. San Diego, CA. May 2019.
3. Secuado prescribing information. Hisamitsu Pharmaceutical Co., Inc. Japan Saga Tosu. October 2019.
4. Caplyta prescribing information. Intra-Cellular Therapies, Inc. New York, NY. December 2021.
5. Saphris prescribing information. Allergan USA, Inc. Irvine, CA. February 2017.
6. Invega Hafyera prescribing information. Janssen Pharmaceuticals, Inc. Titusville, NJ. September 2021.
7. Lybalvi prescribing information. Alkermes, Inc. Waltham, MA. May 2021.

4 . Revision History

Date	Notes
12/15/2023	Added Optum RX EHB formulary to guideline.

Authorized Brand Alternative (ABA) Policy



Prior Authorization Guideline

Guideline ID	GL-136644
Guideline Name	Authorized Brand Alternative (ABA) Policy

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/13/2020
P&T Revision Date:	03/18/2020 ; 02/18/2021 ; 02/17/2022 ; 06/15/2022 ; 10/19/2022 ; 01/18/2023 ; 02/16/2023 ; 03/15/2023 ; 06/21/2023 ; 08/17/2023 ; 12/13/2023

1 . Indications

Drug Name: Fluticasone and Vilanterol inhalation powder
Asthma Indicated for once-daily treatment of asthma in patients aged 18 years and older.
Chronic Obstructive Pulmonary Disease Indicated for long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD).
Drug Name: Fluticasone and Salmeterol HFA inhalation aerosol
Asthma For treatment of asthma in adult and adolescent patients aged 12 years and older.
Drug Name: Insulin Glargine Injection Solution, Insulin Glargine Solostar Injection
Diabetes Mellitus Indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Limitations of use: Insulin glargine is not recommended for the treatment of diabetic ketoacidosis.

Drug Name: Insulin Degludec Injection Solution, Insulin Degludec Flextouch Injection
Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis.
Drug Name: Insulin Aspart Injection Solution, Insulin Aspart Flexpen, Insulin Aspart Penfill, Insulin Aspart 70/30 Injection Solution, Insulin Aspart 70/30 Flexpen, Novolog Relion, Novolog Relion Flexpen, Novolog Relion 70/30, Novolog Relion 70/30 Flexpen
Diabetes Mellitus Indicated to improve glycemic control in adults and children with diabetes mellitus. Limitations of Use: 1) Insulin Aspart Protamine and Insulin Aspart Injactable Suspension Mix 70/30 is not recommended for the treatment of diabetic ketoacidosis. 2) The proportions of rapid-acting and long-acting insulins in Insulin Aspart Protamine and Insulin Aspart Injactable Suspension Mix 70/30 are fixed and do not allow for basal versus prandial dose adjustments.
Drug Name: Insulin Lispro Kwikpen, Insulin Lispro Jr Kwikpen, Insulin Lispro 75/25 Kwikpen
Diabetes Mellitus Indicated to improve glycemic control in adults and children with diabetes mellitus. Limitations of Use: the proportions of rapid-acting and intermediate-acting insulins in Insulin Lispro Protamine and Insulin Lispro Injactable Suspension Mix75/25 are fixed and do not allow for basal versus prandial dose adjustments.

2 . Criteria

Product Name: Brand Insulin Glargine, Brand Insulin Glargine Solostar, Brand Fluticasone-Vilanterol, Brand Insulin Degludec, Brand Insulin Aspart, Brand Insulin Lispro, Novolog Relion, Brand Fluticasone-Salmeterol HFA	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Requested drug is FDA-approved for the condition being treated</p> <p style="text-align: center;">OR</p>	

1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

2 - At least 6 months use of the Brand product* within the previous 365 days (document drug, duration, dose and date of use)

AND

3 - Both of the following:

3.1 Documentation provided stating the Brand product has not been effective

AND

3.2 Justification provided for why the authorized brand alternative (ABA) is expected to provide benefit when the Brand product has not been shown to be effective

Notes

*See table in background section for a list of the target ABAs and their associated Brand products.

3 . Background

Benefit/Coverage/Program Information	
Authorized Brand Alternative (ABA) and their respective Brand products	
Authorized Brand Alternative (ABA)	Brand product
Insulin Glargine	Lantus
Fluticasone-Vilanterol	Breo Ellipta
Insulin Degludec	Tresiba
Insulin Lispro	Humalog

Insulin Aspart, Novolog Relion	Novolog
Fluticasone-Salmeterol HFA	Advair HFA

4 . References

1. Insulin Glargine/Insulin Glargine Solostar. Winthrop U.S. Bridgewater, New Jersey. January 2021.
2. Fluticasone-Vilanterol Prescribing Information. Prasco Laboratories. Mason, Ohio. February 2022.
3. Insulin Degludec/Insulin Degludec Flextouch Prescribing Information. Novo Nordisk Pharma, Inc. Plainsboro, NJ. July 2022.
4. Insulin Aspart Protamine & Insulin Aspart Mix 70/30. Novo Nordisk Pharma, Inc. Plainsboro, New Jersey. October 2020.
5. Insulin Aspart Injection/Flexpen/Penfill. Novo Nordisk Pharma, Inc. Plainsboro, New Jersey. November 2019.
6. Insulin Lispro Injection/Kwikpen/Jr Kwikpen. Eli Lilly and Company. Indianapolis, IN. February 2020.
7. Insulin Lispro Protamine & Insulin Lispro Mix 75/25 Kwikpen. Eli Lilly and Company. Indianapolis, IN. February 2020.
8. Fluticasone and Salmeterol HFA Prescribing Information. Prasco Laboratories. Mason, Ohio. August 2022.

5 . Revision History

Date	Notes
11/23/2023	Removed Brand Fluticasone HFA as target from GL.

Azole Antifungals - PA, NF



Prior Authorization Guideline

Guideline ID	GL-134054
Guideline Name	Azole Antifungals - PA, NF

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/18/2021 ; 02/18/2021 ; 08/19/2021 ; 06/16/2021 ; 02/17/2022 ; 07/20/2022 ; 01/18/2023 ; 02/16/2023 ; 11/16/2023

1 . Indications

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

<p>in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)</p>
<p>Drug Name: Sporanox Pulse Pak (itraconazole)</p>
<p>Onychomycosis of the fingernail Indicated for the treatment of the following fungal infection in non-immunocompromised patients: Onychomycosis of the fingernail due to dermatophytes (Tinea unguium)</p>
<p>Drug Name: Sporanox (itraconazole) oral solution</p>
<p>Oropharyngeal and esophageal candidiasis Indicated for the treatment of oropharyngeal and esophageal candidiasis.</p>
<p>Drug Name: Tolsura (itraconazole) capsules</p>
<p>Blastomycosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Blastomycosis, pulmonary and extrapulmonary.</p> <p>Histoplasmosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Histoplasmosis, including chronic cavitory pulmonary disease and disseminated, nonmeningeal histoplasmosis.</p> <p>Aspergillosis Indicated for the treatment of the following fungal infection in immunocompromised and non-immunocompromised patients: Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or refractory to amphotericin B therapy.</p>
<p>Drug Name: Noxafil (posaconazole) tablets</p>
<p>Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in adult and pediatric patients 2 years of age and older who weigh greater than 40 kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.</p> <p>Prophylaxis of Candida infection Indicated for prophylaxis of invasive Candida infections in adult and pediatric patients 2 years of age and older who weigh greater than 40kg, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.</p> <p>Treatment of Invasive Aspergillosis Indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older.</p>
<p>Drug Name: Noxafil (posaconazole) oral suspension</p>
<p>Prophylaxis of Aspergillus infection Indicated for prophylaxis of invasive Aspergillus infections in patients 13 years of age and older, who are at high risk of developing these</p>

infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

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

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

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

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

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

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

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

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

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

Drug Name: Cresemba (isavuconazonium sulfate) capsules

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

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

2 . Criteria

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

Product Name: Brand Sporanox capsules, generic itraconazole capsules, or Sporanox Pulse Pak	
Diagnosis	Fingernail Onychomycosis
Approval Length	1 Month [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of fingernail onychomycosis as confirmed by one of the following:</p> <ul style="list-style-type: none"> • Positive potassium hydroxide (KOH) preparation • Fungal culture • Nail biopsy <p style="text-align: center;">AND</p> <p>2 - The patient's condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, wearing shoes, or appropriately manicuring nails) [4]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine</p>	

Product Name: Brand Sporanox capsules or generic itraconazole capsules	
Diagnosis	Toenail Onychomycosis
Approval Length	3 Month [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of toenail onychomycosis as confirmed by one of the following:</p> <ul style="list-style-type: none"> • Positive potassium hydroxide (KOH) preparation • Fungal culture 	

<ul style="list-style-type: none"> Nail biopsy <p style="text-align: center;">AND</p> <p>2 - The patient’s condition is causing debility or a disruption in their activities of daily living (e.g., limitations to manual dexterity, walking, standing, wearing shoes, or appropriately manicuring nails) [4]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine</p>
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Product Name: Brand Sporanox oral solution or generic itraconazole oral solution	
Diagnosis	Candidiasis (esophageal or oropharyngeal)
Approval Length	1 month [E, F]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of esophageal candidiasis</p> <p style="text-align: center;">OR</p> <p>1.2 Diagnosis of oropharyngeal candidiasis (OPC)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <ul style="list-style-type: none"> Trial and failure, contraindication, or intolerance to fluconazole Susceptibility results demonstrate resistance to fluconazole 	

Product Name: Tolsura	
Approval Length	6 months [5, 10-12, B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following fungal infections:</p> <ul style="list-style-type: none"> • Blastomycosis • Histoplasmosis • Aspergillosis <p style="text-align: center;">AND</p> <p>2 - Trial and failure or intolerance to generic itraconazole capsules</p>	

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

- Susceptibility results demonstrate resistance to fluconazole

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

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

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

- Aspergillus
- Candida

AND

2 - One of the following:

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

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

OR

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

OR

2.3 For Noxafil PowderMix, both of the following:

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

AND

3 - One of the following:

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

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

OR

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

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet, Noxafil oral suspension, Noxafil PowderMix	
Diagnosis	Prophylaxis of systemic fungal infections
Approval Length	6 Months [B-D]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Used as prophylaxis of invasive fungal infections caused by one of the following:</p> <ul style="list-style-type: none">• Aspergillus• Candida <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 For Noxafil (posaconazole) oral tablet, both of the following:</p> <ul style="list-style-type: none">• Patient is 2 years of age and older• Patient weighs greater than 40kg <p style="text-align: center;">OR</p> <p>2.2 For Noxafil oral suspension, patient is 13 years of age and older</p> <p style="text-align: center;">OR</p> <p>2.3 For Noxafil PowderMix, both of the following:</p> <ul style="list-style-type: none">• Patient is 2 years of age and older• Patient weighs 40 kg or less <p style="text-align: center;">AND</p>	

3 - Submission of medical records (e.g., chart notes) documenting one of the following:

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

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

OR

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

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

Product Name: Brand Noxafil oral tablet, generic posaconazole oral tablet	
Diagnosis	Treatment of systemic fungal infections
Approval Length	3 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of invasive aspergillosis</p>	

AND

2 - Patient is 13 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension

Diagnosis	Invasive Aspergillosis
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Approval Length	6 Months [16, B-D]
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of invasive aspergillosis

AND

2 - Patient is 2 years of age and older

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension

Diagnosis	Serious Fungal Infections
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Approval Length	6 Months [16, B-D]
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of serious fungal infections (e.g., *Scedosporium apiospermum*, *Fusarium* species including *Fusarium solani*)

AND

2 - Patient is 2 years of age and older

AND

3 - Patient is intolerant of, or refractory to, other therapy (e.g., amphotericin B)

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension

Diagnosis	Candidemia in non-neutropenic patients and other deep tissue Candida infections
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Approval Length	1 Month [H, 16]
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of one of the following:

- Candidemia
- Deep tissue Candida infection (e.g., disseminated in skin, infection in abdomen, kidney, bladder wall, and wounds)

AND

2 - Patient is non-neutropenic

AND

3 - Patient is 2 years of age and older

AND

4 - One of the following:

- Trial and failure, contraindication or intolerance to fluconazole [I]

- Susceptibility results demonstrate resistance to fluconazole [K]

Product Name: Brand Vfend oral tablet, generic voriconazole oral tablet, Brand Vfend oral suspension, generic voriconazole oral suspension	
Diagnosis	Esophageal Candidiasis
Approval Length	1 Month [H, 16]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of esophageal candidiasis</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age and older</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <ul style="list-style-type: none"> • Trial and failure, contraindication, or intolerance to fluconazole • Susceptibility results demonstrate resistance to fluconazole 	

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

- Invasive mucormycosis

AND

2 - Patient is 18 years of age and older

3 . Endnotes

- A. Fingernail infections are usually reevaluated 18 weeks or longer after completion of therapy. Toenail infections are usually reevaluated 6-9 months after completion of therapy. [5] Indeed, considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [6] Reports of long-term follow-up of treated patients have recently been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [8]
- B. The optimal duration of therapy for aspergillosis has not been defined. Most clinicians treat infections (pulmonary) until resolution or stabilization of clinical and radiographic manifestations. The IDSA recommends a minimal treatment period of 6 – 12 weeks in immunocompetent patients for invasive conditions. [11]
- C. According to the IDSA guidelines for aspergillosis, duration of therapy for most conditions for aspergillosis has not been optimally defined. Most experts attempt to treat pulmonary infection until resolution or stabilization of all clinical and radiographic manifestations. Other factors include site of infection (e.g., osteomyelitis), level of immunosuppression, and extent of disease. Reversal of immunosuppression, if feasible, is important for a favorable outcome for invasive aspergillosis.” [11]
- D. According to the IDSA guidelines for the treatment of aspergillosis, both Amphotericin B and itraconazole are listed as second line treatment options for the treatment of invasive disease. [11]
- E. For fluconazole-refractory OPC, either itraconazole or posaconazole for up to 28 days is recommended. For fluconazole-refractory esophageal candidiasis, itraconazole or voriconazole for 14 to 21 days is recommended. [3, 5]
- F. Patients may be expected to relapse shortly after discontinuing therapy with Sporanox oral solution. Limited data on the safety of long-term use (> 6 months) of Sporanox Oral Solution are available at this time. [2]
- G. NCCN recommends secondary prophylaxis with an appropriate antifungal agent in patients with prior chronic disseminated candidiasis or with invasive filamentous fungal infection during subsequent cycles of chemotherapy or HSCT. In patients with invasive aspergillosis before HSCT, antifungal therapy for more than a month and resolution of radiologic abnormalities correlate with a lower likelihood of post-transplant recurrence of infection. Secondary prophylaxis with a mold-active agent is advised for the entire period of immunosuppression. Secondary prophylaxis is generally administered for the duration of immunosuppression. Per recommendation from an infectious disease specialist, posaconazole is used for secondary prophylaxis of prior fungal infections. [15]

- H. Voriconazole prescribing information states that for candidemia in non-neutropenic patients and other deep tissue *Candida* infections, patients should be treated for at least 14 days following resolution of symptoms or following last positive culture, whichever is long. For esophageal candidiasis, patients should be treated for a minimum of 14 days and for at least 7 days following resolution of symptoms. [16]
- I. According to the 2016 IDSA guideline for candidemia in nonneutropenic patients, fluconazole, intravenous or oral, is an acceptable alternative to an echinocandin (e.g., caspofungin, micafungin, anidulafungin) in patients who are not critically ill and who are considered unlikely to have fluconazole-resistant *Candida* species. Voriconazole is effective for candidemia, however, offers little advantage over fluconazole as the initial therapy. [5]
- J. According to the 2016 IDSA guideline for the treatment of esophageal candidiasis, oral fluconazole 200-400 mg for 14 to 21 days is strongly recommended (high-quality evidence). Intravenous fluconazole may be used in patients who cannot tolerate oral therapy. For fluconazole-refractory disease, voriconazole either intravenous or oral is recommended. [5]
- K. Of the *Candida* species, *C. krusei* and *C. glabrata* are the two species with higher likelihood of fluconazole-resistance for serious candida infections due to widespread azole treatment. In these cases, voriconazole may be used as oral therapy in patients with infections due to *C. krusei* or fluconazole-resistant, voriconazole-susceptible *C. glabrata* infections. [5]

4 . References

1. Sporanox Capsules Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. December 2022.
2. Sporanox Oral Solution Prescribing Information. Janssen Pharmaceuticals, Inc.; Titusville, NJ. December 2022.
3. Ely J, Rosenfeld S, Stone M. Diagnosis and Management of Tinea Infections. Aafp.org. <https://www.aafp.org/afp/2014/1115/p702.html>. Published 2014. Accessed October 28, 2019
4. Gupta A, Mays R. The Impact of Onychomycosis on Quality of Life: A Systematic Review of the Available Literature. *Skin Appendage Disord*. 2018;4(4):208-216. doi:10.1159/000485632
5. Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2016;62:e1-50.
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7. McEvoy GK. AHFS Drug Information 2005. Bethesda, MD: American Society of Health-System Pharmacists, Inc; 2005.
8. Sigurgeirsson B, Olafsson JH, Steinsson JP, et al. Long-term effectiveness of treatment with terbinafine vs. itraconazole in onychomycosis: a 5-year blinded prospective follow-up study. *Arch Dermatol*. 2002;138:353-7.
9. Roberts DT, Taylor WD, Boyle J. Guidelines for treatment of onychomycosis. *Br J Dermatol*. 2003;148:402-410.

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11. Wheat LJ, Freifeld AG, Kleiman MB, et al. Clinical practice guidelines for the management of patients with histoplasmosis: 2007 update by the Infectious Diseases Society of America. Clin Infect Dis. 2007;45:807-825.
12. Patterson TF, Thompson GR, Denning DW, et al. Practice guidelines for the diagnosis and management of Aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis. 2016;63(4):e1-60.
13. Tolsura Prescribing Information. Mayne Pharma; Greenville, NC. April 2022.
14. Noxafil Prescribing Information. Merck Sharp & Dohme Corp.; Whitehouse Station, NJ. September 2022.
15. Per Clinical Consultation with an Infectious Disease Specialist. January 24, 2014.
16. Voriconazole Tablet Prescribing Information. Ajanta Pharma Limited.; Bridgewater, NJ. November 2022.
17. Cresemba Prescribing Information. Astellas Pharma US., Inc. Northbrook, IL. November 2022.
18. Vfend Prescribing Information. Roerig. New York, NY. October 2022.

5 . Revision History

Date	Notes
9/29/2023	Addition of Cresemba 74.5mg capsules

Banzel (rufinamide)

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Prior Authorization Guideline

Guideline ID	GL-133016
Guideline Name	Banzel (rufinamide)

Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

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

2 . Criteria

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

<p>1 - Diagnosis of seizures associated with Lennox-Gaustaut Syndrome (LGS)</p> <p style="text-align: center;">AND</p> <p>2 - Used as adjunctive therapy</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p>4.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate)</p> <p style="text-align: center;">OR</p> <p>4.2 For continuation of prior therapy if the patient is established on Brand Banzel</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with a neurologist</p>

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

AND
2 - Used as adjunctive therapy
AND
3 - Patient is 1 year of age or older
AND
3 - One of the following:
<p>3.1 Trial of and inadequate response to, contraindication, or intolerance to ONE generic formulary anticonvulsant (e.g., topiramate, lamotrigine, valproate) other than generic rufinamide</p>
OR
3.2 For continuation of prior therapy if the patient is established on generic rufinamide
AND
5 - Prescribed by or in consultation with a neurologist

Product Name: Brand Banzel, generic rufinamide	
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. Banzel Prescribing Information. Eisai Inc. Woodcliff, NJ. April 2020.

4 . Revision History

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

Blood Glucose Monitor & Test Strips - ST, QL, NF



Prior Authorization Guideline

Guideline ID	GL-125127
Guideline Name	Blood Glucose Monitor & Test Strips - ST, QL, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	4/6/2010
P&T Revision Date:	06/17/2020 ; 08/14/2020 ; 03/17/2021 ; 07/21/2021 ; 09/15/2021 ; 06/15/2022 ; 09/21/2022 ; 01/18/2023 ; 6/21/2023

Note:

This guideline does not apply to continuous glucose monitors.

1 . Indications

Drug Name: Blood glucose monitoring systems

Quantitative measurements of glucose Intended to be used for quantitative measurements of glucose in fresh capillary and/or venous whole blood. Various devices are designed for testing by persons with diabetes or by health care professionals in the home or health care facilities.

2 . Criteria

Product Name: Non-preferred test strip products

Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested product is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Trial to a minimum 90 day supply of both Contour Next and OneTouch test strips within the last 180 days</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 The non-preferred test strip is required because it is the only product that will interface with the member’s insulin pump</p>	

Product Name: Non-Formulary or Excluded test strip products	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming that the non-formulary/excluded test strip is required because it is the only product that will interface with the member’s insulin pump</p>	

Product Name: Preferred or non-preferred test strip products	
Approval Length	12 month(s)
Guideline Type	Quantity Limit

Approval Criteria

1 - Physician confirmation that the patient requires a greater quantity because of more frequent blood glucose testing (e.g., patients on intravenous insulin infusions) [A]

Product Name: Non-Formulary or Excluded meter products

Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Submission of medical records (e.g., chart notes) confirming that the non-formulary/excluded meter is required because it is the only product that will interface with the member's insulin pump

Product Name: Non-preferred meter products

Approval Length	12 month(s)
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Guideline Type	Step Therapy
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Approval Criteria

1 - Requested product is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Minimum 1-day trial of both a Contour Next Blood Glucose Monitoring System (e.g. Contour Next EZ Blood Glucose Monitoring System) and a OneTouch Blood Glucose Monitoring System within the last 365 days

OR

2.2 The non-preferred meter is required because it is the only product that will interface with the member's insulin pump

3 . Endnotes

- A. The evidence regarding the utility and optimal frequency of blood glucose monitoring (BGM) is not well defined for patients who do not use intensive insulin regimens, such as those with type 2 diabetes using oral agents and/or basal insulin [1]. However for most patients using intensive insulin regimens (multiple-dose insulin or insulin pump therapy) BGM should be performed prior to meals and snacks, at bedtime, occasionally postprandially, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to and while performing critical tasks such as driving [1].

4 . References

1. American Diabetes Association (ADA). Diabetes Technology: Standards of Medical Care in Diabetes - 2023. Diabetes Care. 2023;46(suppl 1):S111-S127.

5 . Revision History

Date	Notes
6/22/2023	Annual review: updated trial duration and lookback period for "non-preferred meter products" to 1-day trial within the last 365 days.

Bonjesta, Diclegis (doxylamine/pyridoxine)



Prior Authorization Guideline

Guideline ID	GL-129144
Guideline Name	Bonjesta, Diclegis (doxylamine/pyridoxine)

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	2/25/2016
P&T Revision Date:	07/17/2019 ; 04/15/2020 ; 06/17/2020 ; 08/19/2021 ; 08/18/2022 ; 8/17/2023

1 . Indications

Drug Name: Bonjesta, Diclegis (doxylamine succinate and pyridoxine hydrochloride)
Nausea and vomiting of pregnancy Indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Limitations of Use: Bonjesta and Diclegis have not been studied in women with hyperemesis gravidarum.

2 . Criteria

Product Name: Bonjesta, Brand Diclegis, Generic doxylamine/pyridoxine delayed-release	
Approval Length	9 Months
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of nausea and vomiting of pregnancy

AND

2 - Trial and failure or intolerance to generic doxylamine and generic pyridoxine (Vitamin B6) taken together [5, 7]

3 . Endnotes

- A. Bonjesta and Diclegis (doxylamine succinate/pyridoxine hydrochloride) are contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs), which prolong and intensify the anticholinergic (drying) effects of antihistamines. [1, 6]

4 . References

1. Diclegis prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. June 2023.
2. ACOG Practice Bulletin. Nausea and vomiting of pregnancy. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2018; 131(1): 190-193. (Practice Bulletin No. 189)
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4. Ebrahimi N, Maltepe C, Einarson A. Optimal management of nausea and vomiting of pregnancy. Int J Womens Health. 2010; 2: 241–248.
5. Matthews A, Haas DM, O'Mathúna DP, et al. Interventions for nausea and vomiting in early pregnancy. Cochrane Database Syst Rev. 2015 Sep 8; 9:CD007575.
6. Bonjesta prescribing information. Duchesnay USA, Inc. Bryn Mawr, PA. October 2022.
7. Campbell K, Rowe H, Azzam H, Lane C. The Management of Nausea and Vomiting of Pregnancy. Journal of Obstetrics and Gynaecology Canada. 2016;38(12):1127-1137. doi:10.1016/j.jogc.2016.08.009

5 . Revision History

Date	Notes
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7/31/2023	2023 UM Annual Review. No criteria changes. Updated references
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Botox (onabotulinumtoxinA)



Prior Authorization Guideline

Guideline ID	GL-135652
Guideline Name	Botox (onabotulinumtoxinA)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	3/17/2000
P&T Revision Date:	10/16/2019 ; 12/18/2019 ; 07/15/2020 ; 09/16/2020 ; 12/16/2020 ; 04/21/2021 ; 07/21/2021 ; 04/20/2022 ; 07/20/2022 ; 07/19/2023 ; 7/19/2023

1 . Indications

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

controlled studies.

Spasticity Indicated for the treatment of spasticity in patients 2 years of age and older. Limitations of use: Botox has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture.

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

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

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

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

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

Drug Name: Botox Cosmetic (onabotulinumtoxin A)

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

2 . Criteria

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Neuromuscular and Autonomic Disorders
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Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Blepharospasm associated with dystonia (e.g., benign essential blepharospasm) • Cervical dystonia (also known as spasmodic torticollis) • Spasticity • Strabismus • VII cranial nerve disorders (hemifacial spasms) 	

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

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of primary axillary hyperhidrosis [G]

AND

2 - One of the following:

2.1 Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) [A, 1, 4]

OR

2.2 Skin maceration with secondary infection [5]

AND

3 - Trial and failure, contraindication, or intolerance to topical prescription strength drying agents [e.g., Drysol, Hypercare, Xerac AC (aluminum chloride hexahydrate)]

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Primary Axillary Hyperhidrosis
Approval Length	1 Time(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - At least a 2-point improvement in HDSS [1, 4]</p> <p style="text-align: center;">AND</p> <p>2 - At least 3 months have or will have elapsed since the last series of injections [1, 4]</p>	

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Migraine
Approval Length	3 Month [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic migraines [I]</p> <p style="text-align: center;">AND</p> <p>2 - Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [M]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [N]</p> <p style="text-align: center;">AND</p> <p>4 - Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [1, 13-16, L]</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following specialists:</p> <ul style="list-style-type: none"> • Neurologist • Pain specialist • Headache specialist <p style="text-align: center;">AND</p>	

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

6.1 One of the following:

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

OR

6.2 One of the following:

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

OR

6.3 One of the following:

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

OR

6.4 One of the following:

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

AND

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

- Aimovig

- Ajovy

Product Name: Botox (Excluded: Botox Cosmetic)

Diagnosis	Chronic Migraine
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity [19]

AND

2 - Use of acute migraine medications (e.g., NSAIDS, triptans) has decreased since the start of therapy

AND

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

- Neurologist
- Pain specialist
- Headache specialist

AND

4 - Patient continues to be monitored for medication overuse headache (MOH) [M]

AND

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

- Aimovig
- Ajovy

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Urinary Incontinence associated with a Neurologic Condition OR Overactive Bladder with Symptoms OR Neurogenic Detrusor Overactivity (NDO)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following conditions: [1, 3, E, F]</p> <ul style="list-style-type: none"> • Urinary incontinence that is associated with a neurologic condition (e.g., spinal cord injury, multiple sclerosis) • Overactive bladder with symptoms (e.g., urge urinary incontinence, urgency, and frequency) • Neurogenic detrusor overactivity (NDO) <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with a urologist</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to at least one oral anticholinergic (antispasmodic or antimuscarinic) agent [e.g., Bentyl (dicyclomine), Donnatal (atropine/ scopolamine/ hyoscyamine/ phenobarbital), Levsin/Levsinex (hyoscyamine), Ditropan (oxybutynin), Enablex (darifenacin), or VESIcare (solifenacin)]</p> <p style="text-align: center;">AND</p>	

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

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

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic anal fissure [8, 9]</p> <p style="text-align: center;">AND</p> <p>2 - At least 2 months of one of the following symptoms:</p>	

- Nocturnal pain and bleeding
- Postdefecation pain

AND

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

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

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Chronic Anal Fissure (Off-Label)
Approval Length	3 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <ul style="list-style-type: none"> • Incomplete healing of fissure • Recurrence of fissure <p style="text-align: center;">AND</p> <p>2 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p> <p>3 - At least 3 months have or will have elapsed since the last series of injections</p>	

Product Name: Botox (Excluded: Botox Cosmetic)
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Diagnosis	Chronic Back Pain [D] (Off-Label)
Approval Length	1 treatment session (series of injections) [K]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of low back pain</p> <p style="text-align: center;">AND</p> <p>2 - Low back pain has lasted for greater than or equal to six (6) months</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following specialists:</p> <ul style="list-style-type: none"> • Neurologist • Neurosurgeon • Orthopedist • Pain specialist <p style="text-align: center;">AND</p> <p>4 - Trial and failure (at least 3 months), contraindication, or intolerance to both of the following conventional therapies: [10-12]</p> <ul style="list-style-type: none"> • At least one oral NSAID medication • At least one opioid medication <p style="text-align: center;">AND</p> <p>5 - Trial and failure or inadequate response to one of the following: [10]</p> <ul style="list-style-type: none"> • Physical therapy 	

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

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

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

1 - Diagnosis of achalasia

AND

2 - One of the following:

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

- Pneumatic dilation
- Myotomy

OR

2.2 Prior dilation caused esophageal perforation

OR

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

- Epiphrenic diverticulum
- Hiatal hernia

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	Achalasia (Off-Label)
Approval Length	6 Month [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates improvement or reduction in symptoms of achalasia (i.e., dysphagia, regurgitation, chest pain)</p>	

AND

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

Product Name: Botox (Excluded: Botox Cosmetic)	
Diagnosis	All other diagnoses
Approval Length	6 months unless the FDA-approved treatment duration is less than 6 months. If FDA-approved treatment duration is less than 6 months, utilize the FDA-approved duration for authorization period.
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis is consistent with an indication listed in the product’s FDA-approved prescribing information (or package insert)</p> <p style="text-align: center;">AND</p> <p>1.1.2 Additional requirements listed in the “Indications and Usage” and “Dosage and Administration” sections of the prescribing information (or package insert) have been met (e.g.: first line therapies have been tried and failed, any testing requirements have been met, etc)</p> <p style="text-align: center;">OR</p> <p>1.2 Meets the off-label administrative guideline criteria</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to two appropriate formulary alternatives (if available)</p>	

Product Name: All Products	
Diagnosis	Cosmetic Use
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Requests for coverage of any Botox product for treating the appearance of facial lines are not authorized and will not be approved. These uses are considered cosmetic only.</p>	

3 . Endnotes

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

injury, open-label clinical studies showed improvements in urodynamic parameters [recommendation for DSD: Adult, Class IIb, Category B]. For NDO, the use of BoNT (refractory to antispasmodics) in a randomized, double-blind, placebo-controlled clinical trial of 59 patients (n = 53 with spinal cord injury and n = 6 with multiple sclerosis) showed significant improvement in daily incontinence episodes in weeks 1 through 24 (except for weeks 12 and 18) compared to placebo [recommendation for NDO: Adult, Class IIb, Category B]. [12]

- G. The safety and effectiveness of Botox for hyperhidrosis in areas other than the axillae have not been established. [1]
- H. Clinical benefit from prophylactic therapy may take as long as 2 to 3 months to manifest. [17, 18] Recommended first-line agents for the prevention of migraine headache are atenolol, nadolol, propranolol, timolol, amitriptyline, venlafaxine, topiramate, divalproex sodium, and sodium valproate. [17]
- I. Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies. [1] An evidence-based review by the American Academy of Neurology determined that, based on available evidence, Botox was probably ineffective in episodic migraine and tension-type headaches, and should not be considered in patients with these conditions. [12]
- J. The effects of Botox in reducing the frequency of headache days in the PREEMPT trial and in the pooled analysis of the PREEMPT trials were very modest. Given the experience and evidence we have for other prophylactic treatments in the management of migraine, which are supported by national guidelines, it is reasonable to require failure with other prophylactic treatments before approving use of Botox. [17]
- K. A single small randomized trial (n = 31) compared paravertebral injections of botulinum toxin with saline injections and found significant benefit of botulinum toxin up to eight weeks after injection. There is currently no consensus on number of injections or treatment length for low back pain. [12]
- L. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [20]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.
- M. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [20]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
- N. The safety and effectiveness of Botox for chronic headache in patients below the age of 18 years have not been established. In a 12-week, multicenter, double-blind, placebo-controlled clinical trial, 123 adolescent patients (ages 12 to below 18 years) with chronic migraine were randomized to receive Botox 74 Units, Botox 155 Units, or placebo, for one injection cycle. This trial did NOT establish the efficacy of Botox, compared with placebo, for the prophylaxis of headaches in adolescents with chronic migraine. [1]
- O. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], and beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol] [21]. They also support the use of Botox (onabotulinumtoxin A) as an efficacious treatment option for chronic migraine.

Botox (onabotulinumtoxin A) is not however recommended for episodic migraine treatment.

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

4 . References

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2. AHFS Drug Information (2005) website. Available at: http://online.lexi.com/lco/action/doc/retrieve/docid/pdh_f/130028?searchUrl=%2Fico%2Faction%2Fsearch%3Fq%3DBotox%26t%3Dname%26va%3DBotox. Accessed June 13, 2023.
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6. Vaezi MF, Pandolfino JE, Vela MF. American College of Gastroenterology Practice Parameter Committee. Diagnosis and management of achalasia. *Am J Gastroenterol* advance online publication, 23 July 2013.
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9. Brisinda G, et al. A comparison of injections of botulinum toxin and topical nitroglycerin ointment for the treatment of chronic anal fissure. *N Engl J Med* 1999;341:65-9.
10. Ney JP, Difazio M, Sichani A, Monacci W, Foster L, Jabbari B. Treatment of chronic low back pain with successive injections of botulinum toxin A over 6 months: a prospective trial of 60 patients. *Clin J Pain* 2006;22(4):363-369.
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12. Naumann M, So Y, Argoff CE et al. Assessment: botulinum neurotoxin in the treatment of autonomic disorder and pain (an evidence-based review): report of the Therapeutics

- and Assessment Subcommittee of the American Academy of Neurology. *Neurology* 2008;70:1707-1714.
13. Aurora SK, Dodick DW, Turkel CC, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 1 trial. *Cephalalgia*. 2010;30:793-803.
 14. Diener HC, Dodick DW, Aurora SK, et al. OnabotulinumtoxinA for treatment of chronic migraine: results from the double-blind, randomized, placebo-controlled phase of the PREEMPT 2 trial. *Cephalalgia*. 2010;30:804-814.
 15. Dodick DW, Turkel CC, DeGryse RE, et al. OnabotulinumtoxinA for treatment of chronic migraine: pooled results from the double-blind, randomized, placebo-controlled phases of the PREEMPT clinical program. *Headache*. 2010;50:921-936.
 16. Per clinical consultation with neurologist, January 7, 2011.
 17. Silberstein SD, Holland S, Freitag F, et al; Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology* 2012 Apr 24;78(17):1337-45.
 18. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison With Other Recent Clinical Practice Guidelines. *Headache* 2012;52:930-945.
 19. Per clinical consultation with neurologist, July 20, 2015.
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 23. National Institute for Health and Care Excellence. Management of migraine (with or without aura). April 17th, 2018. Available at: <https://pathways.nice.org.uk/pathways/headaches/management-of-migraine-with-or-without-aura#path=view%3A/pathways/headaches/management-of-migraine-with-or-without-aura.xml&content=view-node%3Anodes-prophylactic-treatment>. Accessed August 14, 2020.
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5 . Revision History

Date	Notes
10/31/2023	update guideline eff 1/1/2024

Bowel Prep Agents

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Prior Authorization Guideline

Guideline ID	GL-135356
Guideline Name	Bowel Prep Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/14/2019
P&T Revision Date:	07/15/2020 ; 10/21/2020 ; 01/20/2021 ; 04/21/2021 ; 10/20/2021 ; 10/19/2022 ; 09/20/2023 ; 11/16/2023

1 . Indications

Drug Name: Moviprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.
Drug Name: Plenvu
Colonoscopy Indicated for cleansing of the colon in preparation for colonoscopy in adults.
Drug Name: Osmoprep
Colonoscopy Indicated for cleansing of the colon as a preparation for colonoscopy in adults.

2 . Criteria

Product Name: Brand Moviprep, Plenvu, Osmoprep
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Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of a minimum 1 day supply within the last 180 days, contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> • Clenpiq • Suprep • Suflave 	

3 . References

1. Moviprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. June 2023.
2. Plenvu prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. September 2023.
3. Osmoprep prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. March 2019.
4. Suflave prescribing information. Sebelo Pharmaceuticals, Inc. Holbrook, MA. June 2023.

4 . Revision History

Date	Notes
11/1/2023	Program update to remove Suflave

Cabotegravir Containing Agents - PA, NF



Prior Authorization Guideline

Guideline ID	GL-121685
Guideline Name	Cabotegravir Containing Agents - PA, NF

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/17/2021
P&T Revision Date:	04/21/2021 ; 11/18/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 12/14/2022 ; 3/15/2023

1 . Indications

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

HIV-1 Pre-Exposure Prophylaxis Indicated in at-risk adults and adolescents weighing at least 35 kg for short-term pre exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Vocabria may be used as: 1) Oral lead-in to assess the tolerability of cabotegravir prior to administration of Apretude extended-release injectable suspension for HIV-1 PrEP. 2) Oral therapy for patients who will miss planned injection dosing with Apretude for HIV-1 PrEP.

Drug Name: Apretude (cabotegravir) Injection

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

2 . Criteria

Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - All of the following:</p> <p>1.1 Diagnosis of HIV-1 infection</p> <p style="text-align: center;">AND</p> <p>1.2 Patient is 12 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.3 Patient's weight is greater than or equal to 35 kg</p>	

AND

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

AND

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

AND

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

AND

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

OR

2 - For continuation of prior therapy

Notes	*If patient meets criteria above, please approve both Vocabria and Cabenuva at GPI list "CABOTTEGRPA".
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Product Name: Vocabria*, Cabenuva*	
Diagnosis	Treatment of HIV-1 Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary
Approval Criteria	

1 - All of the following:

1.1 Diagnosis of HIV-1 infection

AND

1.2 Patient is 12 years of age or older

AND

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

AND

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

AND

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

AND

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

AND

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

OR

<p>2 - Paid claims or submission of medical records (e.g., chart notes) confirming continuation of prior therapy, defined as no more than a 70-day gap in therapy [A]</p>	
Notes	<p>*If patient meets criteria above, please approve both Vocabria and Ca benuva at GPI list "CABOTTEGRPA".</p>

<p>Product Name: Vocabria**, Apretude**</p>	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection</p> <p style="text-align: center;">AND</p> <p>2 - Patient's weight is greater than or equal to 35 kg</p> <p style="text-align: center;">AND</p> <p>3 - Documentation of both of the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:</p> <ul style="list-style-type: none"> • Negative HIV-1 antigen/antibody test • Negative HIV-1 RNA assay <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p> 4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg</p>	

OR	
<p>4.2 Provider attests to both of the following:</p> <ul style="list-style-type: none"> • Patient would benefit from long-acting injectable therapy over standard oral regimens • Patient would be adherent to testing and dosing schedule 	
Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list “APRETUDEPA”

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

Product Name: Vocabria**, Apretude**	
Diagnosis	HIV-1 Pre-Exposure Prophylaxis
Approval Length	12 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Requested drug is being used for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection</p> <p style="text-align: center;">AND</p> <p>2 - Patient's weight is greater than or equal to 35 kg</p> <p style="text-align: center;">AND</p> <p>3 - Submission of medical records (e.g., chart notes) confirming documentation of both the following U.S. Food and Drug (FDA)-approved test prior to use of Vocabria or Apretude:</p> <ul style="list-style-type: none"> • Negative HIV-1 antigen/antibody test • Negative HIV-1 RNA assay <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following:</p> <p>4.1 Trial of, contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200/300mg</p> <p style="text-align: center;">OR</p> <p>4.2 Both of the following:</p> <ul style="list-style-type: none"> • Patient would benefit from long-acting injectable therapy over standard oral regimens • Patient would be adherent to testing and dosing schedule 	
Notes	**If patient meets criteria above, please approve both Vocabria and Apretude at GPI list "APRETUDEPA"

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

3 . Endnotes

- A. Continuation of therapy for Cabenuva and Vocabria in NF criteria will allow for a 70-day gap to account for the 2-month dosing schedule +/- 7 days. [1]

4 . References

1. Cabenuva Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. April 2022.
2. Vocabria Prescribing Information. ViiV Healthcare Company. Research Triangle Park, NC. March 2022.
3. Apretude Prescribing information. ViiV Healthcare Company. Research Triangle Park, NC. December 2021.

5 . Revision History

Date	Notes
3/15/2023	Annual review - no changes.

Cannabinoids

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Prior Authorization Guideline

Guideline ID	GL-129153
Guideline Name	Cannabinoids

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	10/3/2006
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 11/18/2021 ; 04/20/2022 ; 04/19/2023 ; 8/17/2023

1 . Indications

Drug Name: Marinol (dronabinol) capsule, Syndros (dronabinol) oral solution
Chemotherapy-induced nausea and vomiting Indicated in adults for the treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.
Anorexia in patients with AIDS Indicated in adults for the treatment of anorexia associated with weight loss in patients with Acquired Immune Deficiency Syndrome (AIDS)

2 . Criteria

Product Name: Brand Marinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chemotherapy-induced nausea and vomiting</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to formulary generic dronabinol capsules*</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]</p> <ul style="list-style-type: none"> • Ativan (lorazepam) • Compazine (prochlorperazine) • Decadron (dexamethasone) • Haldol (haloperidol) • Phenergan (promethazine) • Reglan (metoclopramide) • Zyprexa (olanzapine) 	
Notes	*This product may require prior authorization.

Product Name: Syndros	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - One of the following:

2.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

2.2 Patient is unable to swallow capsules

AND

3 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

4 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Notes

*This product may require prior authorization.

Product Name: Generic dronabinol	
Diagnosis	Chemotherapy-induced nausea and vomiting
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chemotherapy-induced nausea and vomiting

AND

2 - Trial and failure, contraindication, or intolerance to a 5HT-3 receptor antagonist (e.g., Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]) [1]

AND

3 - Trial and failure, contraindication, or intolerance to one of the following: [1, A]

- Ativan (lorazepam)
- Compazine (prochlorperazine)
- Decadron (dexamethasone)
- Haldol (haloperidol)
- Phenergan (promethazine)
- Reglan (metoclopramide)
- Zyprexa (olanzapine)

Product Name: Brand Marinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of anorexia with weight loss in patients with AIDS</p> <p style="text-align: center;">AND</p> <p>2 - Patient is on antiretroviral therapy [8, 9]</p>	

AND	
3 - One of the following [3-6, 9]:	
3.1 Patient is 65 years of age or greater	
OR	
3.2 Both of the following:	
<ul style="list-style-type: none"> • Patient is less than 65 years of age • Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension 	
AND	
4 - Trial and failure or intolerance to formulary generic dronabinol capsules*	
Notes	*This product may require prior authorization.

Product Name: Syndros	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of anorexia with weight loss in patients with AIDS</p> <p style="text-align: center;">AND</p> <p>2 - Patient is on antiretroviral therapy [8, 9]</p> <p style="text-align: center;">AND</p>	

3 - One of the following [3-4, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

AND

4 - One of the following:

4.1 Trial and failure or intolerance to formulary generic dronabinol capsules*

OR

4.2 Patient is unable to swallow capsules

Notes	*This product may require prior authorization.
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Product Name: Generic dronabinol	
Diagnosis	Anorexia in Patients with AIDS
Approval Length	3 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of anorexia with weight loss in patients with AIDS</p> <p style="text-align: center;">AND</p> <p>2 - Patient is on antiretroviral therapy [8, 9]</p>	

AND

3 - One of the following [3-6, 9]:

3.1 Patient is 65 years of age or greater

OR

3.2 Both of the following:

- Patient is less than 65 years of age
- Trial and failure, contraindication, or intolerance to megestrol acetate oral suspension

3 . Endnotes

- A. Per NCCN, cannabinoids are agents that can be used for breakthrough treatment. Other agents used for breakthrough treatment include: phenothiazines (prochlorperazine, promethazine), prokinetic agents (metoclopramide), antipsychotic agents (haloperidol, olanzapine), corticosteroids (dexamethasone), benzodiazepines (lorazepam), and 5-HT₃ receptor antagonists (dolasetron, granisetron, ondansetron). [1]

4 . References

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5 . Revision History

Date	Notes
8/8/2023	Updated clinical criteria

CGRP Inhibitors - PA, NF



Prior Authorization Guideline

Guideline ID	GL-135376
Guideline Name	CGRP Inhibitors - PA, NF

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	07/17/2019 ; 11/14/2019 ; 01/15/2020 ; 03/18/2020 ; 05/14/2020 ; 08/13/2020 ; 12/16/2020 ; 01/20/2021 ; 07/21/2021 ; 09/15/2021 ; 11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 02/16/2023 ; 06/21/2023 ; 08/17/2023 ; 11/16/2023

1 . Indications

Drug Name: Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), Vyepti (eptinezumab-jjmr)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Drug Name: Emgality (galcanezumab-gnlm)
Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.
Episodic Cluster Headache Indicated for the treatment of episodic cluster headache in adults.
Drug Name: Nurtec ODT (rimegepant sulfate)

<p>Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.</p> <p>Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.</p>
<p>Drug Name: Qulipta (atogepant)</p>
<p>Preventive Treatment of Migraine Indicated for the preventive treatment of migraine in adults.</p>
<p>Drug Name: Ubrelvy (ubrogepant)</p>
<p>Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.</p>
<p>Drug Name: Zavzpret (zavegepant) nasal spray</p>
<p>Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Zavzpret is not indicated for the preventive treatment of migraine.</p>

2 . Criteria

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Both of the following:</p> <p> 1.1.1 Diagnosis of episodic migraines</p>	

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

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

OR

3.2 One of the following:

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

OR

3.3 One of the following:

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

OR

3.4 One of the following:

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

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Aimovig, Ajovy, or Vyepti	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy

AND

3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Both of the following:</p> <p> 1.1.1 Diagnosis of episodic migraines</p>	

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Two of the following [D, E, F, G, 10]:

3.1 One of the following:

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

OR

3.2 One of the following:

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

OR

3.3 One of the following:

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

OR

3.4 One of the following:

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

AND

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

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.067); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)
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Product Name: Emgality 120 mg/mL	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">AND</p> <p>2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy</p> <p style="text-align: center;">AND</p> <p>3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]</p> <p style="text-align: center;">AND</p> <p>4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines</p>	

AND

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

- Aimovig
- Ajovy

Product Name: Emgality 120 mg/mL

Diagnosis	Preventive Treatment of Migraine
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Guideline Type	Non Formulary
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Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of episodic migraines

AND

1.1.2 Submission of medical records (e.g., chart notes) confirming the patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [A, B, C]

OR

1.2 All of the following:

1.2.1 Submission of medical records (e.g., chart notes) confirming a diagnosis of chronic migraines

AND

1.2.2 Submission of medical records (e.g., chart notes) confirming the patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming two of the following [D, E, F, G, 10]:

3.1 One of the following:

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

OR

3.2 One of the following:

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

OR

3.3 One of the following:

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

OR

3.4 One of the following:

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

AND

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

- Aimovig
- Ajovy

AND

5 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Approval Length: 6 months [E]. *QL Override for Emgality (For new starts only): For migraine, please enter 2 PAs with the same start date as follows: First PA: Approve two pens or syringes per 30 days for 1 month with a fill count of 2 (Loading dose has a MDD of 0.066); Second PA: Approve one pen or syringe per 30 days (no overrides needed) for 6 months. (Emgality 120 mg/mL is hard-coded with a quantity of one prefilled pen/syringe per 30 days)
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Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 Diagnosis of episodic migraines

AND

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.
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Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	12 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">AND</p> <p>2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy</p> <p style="text-align: center;">AND</p> <p>3 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines</p>	
Notes	Nurtec ODT: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 12 months.

Product Name: Nurtec ODT	
Diagnosis	Preventive Treatment of Episodic Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming both of the following:</p> <p>1.1 Diagnosis of episodic migraines</p> <p style="text-align: center;">AND</p>	

1.2 Patient has 4 to 18 migraine days per month, but no more than 18 headache days per month [26]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Notes	Note: For use for preventive treatment of migraine, please enter a quality limit override of #16 tablets per 30 days (MDD, 0.54) for 6 months.
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Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p>	

1.1.1 Diagnosis of episodic migraines

AND

1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]

OR

1.2 All of the following:

1.2.1 Diagnosis of chronic migraines

AND

1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]

AND

1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]

AND

2 - Patient is 18 years of age or older [I]

AND

3 - History of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)

<ul style="list-style-type: none"> Atacand (candesartan) <p style="text-align: center;">AND</p> <p>4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines</p>
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Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">AND</p> <p>2 - Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy</p> <p style="text-align: center;">AND</p> <p>3 - For Chronic Migraine only: Patient continues to be monitored for medication overuse headache (MOH) [H]</p> <p style="text-align: center;">AND</p> <p>4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines</p>	

Product Name: Qulipta	
Diagnosis	Preventive Treatment of Migraine
Approval Length	6 Months [E]
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming one of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Diagnosis of episodic migraines</p> <p style="text-align: center;">AND</p> <p>1.1.2 Patient has 4 to 14 migraine days per month, but no more than 14 headache days per month [28]</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Diagnosis of chronic migraines</p> <p style="text-align: center;">AND</p> <p>1.2.2 Patient has greater than or equal to 15 headache days per month, of which at least 8 must be migraine days for at least 3 months [A]</p> <p style="text-align: center;">AND</p> <p>1.2.3 Medication overuse headache has been considered and potentially offending medication(s) have been discontinued [H]</p> <p style="text-align: center;">AND</p>	

2 - Patient is 18 years of age or older [I]

AND

3 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure (after at least a two month trial), contraindication, or intolerance to TWO of the following [D, E, F, G, 10]:

- Elavil (amitriptyline) or Effexor (venlafaxine)
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate)
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

4 - Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines

Product Name: Emgality 100 mg/mL	
Diagnosis	Episodic Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of episodic cluster headache</p> <p style="text-align: center;">AND</p> <p>2 - Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months [21]</p> <p style="text-align: center;">AND</p>	

3 - Patient is 18 years of age or older [I]

AND

4 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Emgality 100 mg/mL

Diagnosis	Episodic Cluster Headaches
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Approval Length	12 month(s)
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Therapy Stage	Reauthorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity

AND

2 - Medication will not be used in combination with another injectable CGRP inhibitor

Product Name: Nurtec ODT

Diagnosis	Acute Treatment of Migraine
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Approval Length	3 month(s)
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Therapy Stage	Initial Authorization
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Guideline Type	Prior Authorization
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Approval Criteria

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Nurtec ODT

Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines</p>	

Product Name: Nurtec ODT	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [!]</p>	

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Ubrelvy	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of migraine with or without aura

AND

2 - Will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [I]

AND

4 - One of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Ubrelyv	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Will not be used for preventive treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines</p>	

Product Name: Ubrelyv	
Diagnosis	Acute Treatment of Migraine
Approval Length	3 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) confirming a diagnosis of migraine with or without aura</p> <p style="text-align: center;">AND</p>	

2 - Submission of medical records (e.g., chart notes) confirming drug will be used for the acute treatment of migraine

AND

3 - Patient is 18 years of age or older [!]

AND

4 - Paid claims or submission of medical records (e.g., chart notes) confirming one of the following: [24]

- Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan)
- Contraindication to all triptans

AND

5 - Paid claims or submission of medical records (e.g., chart notes) confirming that if patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:

- Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications
- Dapakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications
- Atacand (candesartan) unless there is a contraindication or intolerance to this medication
- Generic lisinopril unless there is a contraindication or intolerance to this medication

AND

6 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine

Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of migraine with or without aura</p> <p style="text-align: center;">AND</p> <p>2 - Will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [I]</p> <p style="text-align: center;">AND</p> <p>4 - One of the following: [24]</p> <ul style="list-style-type: none"> • Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan) • Contraindication to all triptans <p style="text-align: center;">AND</p> <p>5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following: [D, 24]:</p> <ul style="list-style-type: none"> • Elavil (amitriptyline) or Effexor (venlafaxine) unless there is a contraindication or intolerance to these medications • Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate) unless there is a contraindication or intolerance to these medications • A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) unless there is a contraindication or intolerance to these medications • Atacand (candesartan) unless there is a contraindication or intolerance to this medication 	

<ul style="list-style-type: none"> • Generic lisinopril unless there is a contraindication or intolerance to this medication <p style="text-align: center;">AND</p> <p>6 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines</p>

Product Name: Zavzpret	
Diagnosis	Acute Treatment of Migraine
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)</p> <p style="text-align: center;">AND</p> <p>2 - Will not be used for preventive treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Medication will not be used in combination with another CGRP inhibitor for the acute treatment of migraines</p>	

3 . Endnotes

- A. The International Classification of Headache Disorders, 3rd addition (beta version) distinguishes chronic and episodic migraine [11]. Chronic migraine is described as headache occurring on 15 or more days per month for more than 3 months, which has the features of migraine headache on at least 8 days per month. Episodic migraine is not clearly defined, but is applied when a patient is diagnosed with migraine but does not meet criteria for chronic migraine.

- B. While every patient with chronic migraine should receive preventive therapy, not every patient with episodic migraine needs prevention [12]. Appropriate candidates for preventative treatment include those with at least 4 days per month of headache-related disability.
- C. The phase 3 inclusion criteria for the erenumab (LIBERTY, STRIVE, ARISE) and galcanezumab (EVOLVE-1, EVOLVE-2) pivotal trials in episodic migraine required that patients had 4 to 14 migraine days per month [3-9]. The LEADER trial evaluated patients who had failed two to four prior preventive migraine treatments (PMTs). At the start of the trial, 38.6%, 37.8%, and 22.8% of patients had failed two, three, and four prior PMTs, respectively [2].
- D. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan [16, 24].
- E. The US Headache Consortium Consensus (Table e-1) recommends that therapy be initiated with medications that have the highest level of evidence-based therapy while also taking into account patient specific comorbidities [15]. Each medication should be given an adequate trial, it may take two to three months to achieve clinical benefit, and six months to achieve maximal benefit.
- F. The OptumRx clinical team consulted with a neurologist on the prospective review of the CGPR Inhibitors [14]. He confirmed that preventative treatment for chronic migraine and episodic migraine are similar. The choice of preventative medication will not vary much between the episodic vs chronic subtypes. The choice of agent will largely depend more on patient specific factors. Also, he felt that this agent will most likely fall into a similar place in therapy as Botox (onabotulinumtoxin A).
- G. The National Institute for Health and Care Excellence guidelines for the management of migraine recommend Botox (onabotulinumtoxin A) as an option in chronic migraine after failure of at least three other prophylactic medications and that the patient is being managed for medication overuse [13].
- H. Medication overuse headache (MOH) is defined as headache occurring greater than or equal to 15 days per month. It develops as a consequence of regular overuse of acute or symptomatic headache medication for more than 3 months [11]. Current evidence suggests the best treatment strategy is withdrawal of the offending medication.
- I. The safety and effectiveness in pediatric patients has not been established [1, 17-19, 20, 22, 29].
- J. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [25]

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5 . Revision History

Date	Notes
10/24/2023	Update guideline

Ciprofloxacin-Containing Otic Agents

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Prior Authorization Guideline

Guideline ID	GL-129102
Guideline Name	Ciprofloxacin-Containing Otic Agents

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	5/21/1999
P&T Revision Date:	07/15/2020 ; 03/17/2021 ; 07/21/2021 ; 07/20/2022 ; 07/19/2023 ; 8/17/2023

1 . Indications

Drug Name: Cetraxal (ciprofloxacin otic solution)
Acute Otitis Externa Indicated for the treatment of acute otitis externa due to susceptible isolates of <i>Pseudomonas aeruginosa</i> or <i>Staphylococcus aureus</i> .
Drug Name: Ciprodex (ciprofloxacin and dexamethasone otic suspension)
Acute Otitis Media Indicated in pediatric patients (age 6 months and older) with tympanostomy tubes for the treatment of infections caused by susceptible isolates of <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Moraxella catarrhalis</i> , and <i>Pseudomonas aeruginosa</i> .
Acute Otitis Externa Indicated in pediatric (age 6 months and older), adult and elderly patients for the treatment of infections caused by susceptible isolates of <i>Staphylococcus aureus</i> and <i>Pseudomonas aeruginosa</i> .

2 . Criteria

Product Name: Brand Cetraxal	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution</p>	

Product Name: Brand Ciprodex	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 10-day supply) within the past 180 days, contraindication, or intolerance to generic ofloxacin otic solution</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 7-day supply) within the past 180 days, or intolerance to generic ciprofloxacin-dexamethasone otic suspension</p>	

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4 . Revision History

Date	Notes
7/28/2023	Retired ST on generic ciprofloxacin otic agent.

Clinical Duplicates Prior Authorization (PA) Program



Prior Authorization Guideline

Guideline ID	GL-135818
Guideline Name	Clinical Duplicates Prior Authorization (PA) Program

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	10/21/2021
P&T Revision Date:	11/18/2021 ; 01/19/2022 ; 03/16/2022 ; 04/20/2022 ; 05/19/2022 ; 06/15/2022 ; 08/18/2022 ; 09/21/2022 ; 10/19/2022 ; 11/17/2022 ; 04/19/2023 ; 04/19/2023 ; 06/21/2023 ; 10/18/2023 ; 11/16/2023

1 . Criteria

Product Name: Acuvail, Adlarity, Ala-Scalp lotion, Alkindi Sprinkle, Brand Allzital, Alocril, Alex, Analpram-HC lotion, Antara, Aspruzyo Sprinkle, Brand Baclofen, Baclofen suspension, Brand Baclofen oral solution, Brand Fenofibrate micronized capsules, Apexicon E cream, Betoptic-S, Bryhali lotion, Brand Butalbital/apap 50-300 mg capsules, Capex shampoo, Clarinex-D, Conjupri, Consensi, Cordran cream/tape, Cortisone tablets, Brand Cyclobenzaprine/Gabapentin pak 10/300, Brand Decadron, Denavir cream, Dexabliss, Brand Durezol, Durlaza, Dutoprol, Dxevo, Ecoza, Brand Epaned, Ertaczo, Exelderm, Brand Sulconazole nitrate cream/solution, Flector patch, Fleqsuvy susp, Brand Diclofenac epolamine patch, Fosamax+D, Gialax, Gilphex TR, Giltuss, Giltuss TR, Gimoti, Glycate, Brand Glycopyrrolate, Halog ointment/solution, Hemady, Hidex, Impeklo, Inderal XL, Innopran XL, Karbinal ER, Katerzia, Kristalose, Lexette foam, Brand Halobetasol foam, Brand Levamlodipine, Licart patch, Loreev XR, Brand Lotemax gel, Lotemax ointment, Luzu cream, Brand Luliconazole cream, Lyvispah, generic methocarbamol 1000 mg, Brand Mentax cream, Generic metformin 625 mg, Brand Millipred, Motofen, Naprelan, Brand Naproxen ER, Neotuss Plus, Nexiclon XR, Brand Clonidine ER (Nexiclon XR ABA), Brand Nitrofurantoin oral solution,

Brand Norgesic Forte, Brand Orphengesic Forte, Oravig, Ortikos, Otovel, Brand Ciprofloxacin/Fluocinolone PF soln, Oxistat, Ozobax/Ozobax DS, Pandel cream, Pliaglis cream, Pokonza, Brand Lidocaine/Tetracaine cream, Generic prednisolone, Brand Psorcon cream, Qbrelis, Qmiiz ODT, Rayos, Relafen DS, Reltone, Brand Ursodiol, Sancuso, Seglentis, Semprex-D, Sitavig, Sivextro tab, Sorilux, Brand Calcipotriene Aer, Sulfamylon cream, Synera, Taperdex, Brand Trianex oint, Ultravate lotion, Brand Valsartan oral solution, Vanatol LQ, Vanatol S, VTOL, Verdeso, Veregen, Vusion, Brand Miconazole Nitrate/Zinc Oxide/White Petrolatum oint, Xolegel, Yosprala, Brand Aspirin/Omeprazole tab, Zcort, Zilretta inj, Zuplenz

Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Both of the following:

1.1 One of the following:

1.1.1 Both of the following:

1.1.1.1 Requested drug is FDA-approved for the condition being treated

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The

clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.
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Product Name: Abilify Mycite, Spritam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 One of the following:</p> <p>1.1.1 Both of the following:</p> <p>1.1.1.1 Requested drug is FDA-approved for the condition being treated</p>	

AND

1.1.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)

OR

1.1.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

AND

1.2 One of the following:

1.2.1 Patient has failed or has contraindications or intolerance to at least three generic formulary drugs. If only one or only two generic drugs are available, the patient must have failed or had contraindications or intolerance to all available generic formulary drugs. The clinician's judgment should be used to determine appropriate generic formulary drugs for the indication provided.*

OR

1.2.2 Both of the following:

1.2.2.1 Only over-the-counter (OTC) equivalents are available

AND

1.2.2.2 Patient has tried and failed or has contraindications or intolerance to three OTC equivalents. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available OTC equivalents [document drug(s), dose, duration of trial] The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided.*

OR

1.2.3 No formulary or OTC drug is appropriate to treat the patient's condition

OR

1.2.4 For continuation of prior therapy

Notes	*Please consult client-specific resources to determine appropriate generic formulary drugs.
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2 . Revision History

Date	Notes
11/2/2023	Added Pokonza, Ozobax DS, and Brand Baclofen oral solution as targets to program.

Colony-Stimulating Factors (CSFs) - PA, NF



Prior Authorization Guideline

Guideline ID	GL-137568
Guideline Name	Colony-Stimulating Factors (CSFs) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Fulphila (pegfilgrastim-jmdb, G-CSF), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf, G-CSF), Stimufend (pegfilgrastim-fpgk), Ziextenzo (pegfilgrastim-bmez, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Limitations of Use: Pegfilgrastim is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Off Label Uses: Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [1, 33, 35, M]

Treatment of High-Risk Febrile Neutropenia (FN) For the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34, 35]

Drug Name: Granix (tbo-filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to reduce the duration of severe neutropenia in adult and pediatric patients 1 month and older with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Hematopoietic Subsyndrome of Acute Radiation Syndrome To increase survival in patients acutely exposed to myelosuppressive doses of radiation. [16]

Drug Name: Leukine (sargramostim, GM-CSF)

Acute Myeloid Leukemia (AML) Following Induction Chemotherapy Indicated to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infections following induction chemotherapy in adult patients 55 years and older with acute myeloid leukemia (AML).

Autologous Peripheral Blood Progenitor Cell Mobilization and Collection Indicated in adult patients with cancer undergoing autologous hematopoietic stem cell transplantation for the mobilization of hematopoietic progenitor cells into peripheral blood for collection by leukapheresis.

Autologous Peripheral Blood Progenitor Cell and Bone Marrow Transplantation Indicated for the acceleration of myeloid reconstitution following autologous peripheral blood progenitor cell (PBPC) or bone marrow transplantation in adult and pediatric patients 2 years of age and older with non-Hodgkin's lymphoma (NHL), acute lymphoblastic leukemia (ALL) and Hodgkin's lymphoma (HL).

Allogeneic Bone Marrow Transplantation (BMT) Indicated for the acceleration of myeloid reconstitution in adult and pediatric patients 2 years of age and older undergoing allogeneic bone marrow transplantation from HLA-matched related donors.

Allogeneic or Autologous Bone Marrow Transplantation: Treatment of Delayed Neutrophil Recovery or Graft Failure Indicated for the treatment of adult and pediatric patients 2 years and older who have undergone allogeneic or autologous bone marrow transplantation in whom neutrophil recovery is delayed or failed.

Hematopoietic Syndrome of Acute Radiation Syndrome (H-ARS) Indicated to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

Off Label Uses: Febrile Neutropenia (FN), Prophylaxis Has been used in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever [11]

Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-

related neutropenia [37]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neulasta, Neulasta Onpro (pegfilgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Hematopoietic Subsyndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Neupogen (filgrastim, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever.

Patients with Acute Myeloid Leukemia (AML) Receiving Induction or Consolidation Chemotherapy Indicated for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with AML.

Patients with Cancer Undergoing Bone Marrow Transplantation (BMT) Indicated to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation.

Patients Undergoing Autologous Peripheral Blood Progenitor Cell (PBPC) Collection and Therapy Indicated for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

Patients with Severe Chronic Neutropenia (SCN) Indicated for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

Hematopoietic Syndrome of Acute Radiation Syndrome Indicated to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Off Label Uses: Human Immunodeficiency Virus (HIV)-Related Neutropenia Has been prescribed for HIV-related neutropenia. [11-15, 37]

Hepatitis-C Interferon Induced Neutropenia Neupogen has been prescribed for interferon-induced neutropenia in Hepatitis C virus infected patients [4-10, 23, 24]

Treatment of High-Risk Febrile Neutropenia (FN) Has been prescribed for the treatment of FN in patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia who are at high risk for infection-associated complications. [16, 17, 34]

Drug Name: Nivestym (filgrastim-aafi, G-CSF), Zarxio (filgrastim-sndz, G-CSF)

Febrile Neutropenia (FN), Prophylaxis Indicated to decrease the incidence of infection, as manifested by FN, in patients with nonmyeloid malignancies receiving myelosuppressive 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
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient has non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT)</p> <p style="text-align: center;">OR</p> <p>1.2 Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis</p> <p style="text-align: center;">OR</p> <p>1.3 Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy</p>	

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
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Approval Length	3 months or duration of therapy [C]
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Guideline Type	Prior Authorization
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Approval Criteria

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

AND

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

AND

3 - Patient is 55 years of age or older [3, B]

AND

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

Product Name: Neupogen, Nivestym, Releuko, or Zarxio

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

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

AND

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

AND

3 - 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
<p>Approval Criteria</p> <p>1 - Diagnosis of acute myeloid leukemia (AML) [A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient has completed induction or consolidation chemotherapy [27]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with a hematologist/oncologist</p> <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:</p> <ul style="list-style-type: none"> • 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
<p>Approval Criteria</p>	

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 Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Notes

*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro and Udenyca at GPI list "FILGRASTPA".

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo

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 Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

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
- Udenyca

Product Name: Rolvedon	
Diagnosis	Febrile Neutropenia Prophylaxis
Approval Length	3 months or duration of therapy
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Patient will be receiving prophylaxis for febrile neutropenia (FN) due to one of the following:</p> <p>1.1 Patient is receiving National Cancer Institute’s Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer (see Table 1 in Background section) [16-19, 34, D, E]</p> <p style="text-align: center;">OR</p>	

1.2 Patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown [E]

OR

1.3 One of the following:

1.3.1 Patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN (see Table 2 in Background section) [16, 17, 34, I]

OR

1.3.2 Both of the following:

1.3.2.1 Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN (see Table 3 in Background section) [16, J]

AND

1.3.2.2 Patient has one or more risk factors associated with chemotherapy induced infection, FN, or neutropenia [16, 17, 34, K]

OR

1.4 Both of the following:

1.4.1 Patient is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [L]

AND

1.4.2 Patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis) [16, 17, 34]

AND

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

AND

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

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Fulphila, Fylnetra, Granix, Leukine, Neulasta/Neulasta Onpro*, Neupogen, Nivestym, Nyvepria, Releuko, Stimufend, Udenyca*, Zarxio, or Ziextenzo

Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	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, I]

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	
<p>5 - One of the following:</p> <p>5.1 Trial and failure or intolerance to both of the following (applies to Neupogen, Releuko, and Granix only):</p> <ul style="list-style-type: none"> • Nivestym • Zarxio 	
OR	
<p>5.2 Trial and failure or intolerance to both of the following (applies to Fulphila, Fylnetra, Nyvepria, Stimufend, and Ziextenzo only):</p> <ul style="list-style-type: none"> • Neulasta/Neulasta Onpro • Udenyca 	
Notes	*If patient meets criteria above, please approve both Neulasta/Neulasta Onpro and Udenyca at GPI list "FILGRASTPA".

Product Name: Fulphila, Fylnetra, Granix, Neupogen, Nyvepria, Ziextenzo	
Diagnosis	Treatment of High-Risk Febrile Neutropenia (Off-label) [34]
Approval Length	3 Months of duration of therapy
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia (see Table 4 in Background section) [34, I]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of febrile neutropenia (FN)</p>	

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 Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Severe Chronic Neutropenia (SCN)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - For patients with severe chronic neutropenia (SCN) (i.e., congenital, cyclic, and idiopathic neutropenias with chronic absolute neutrophil count [ANC] less than or equal to 500 cells/mm³) [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)
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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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/mm³) [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, Granix 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, Ziextenzo only):

- Neulasta/Neulasta Onpro
- Udenyca

Product Name: Fulphila (Off-Label), Fylnetra (Off-Label), Granix (Off-Label), Neupogen, Nyvepria (Off-Label), Ziextenzo

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, Fylnetra, Nyvepria, and Ziextenzo only):

- Neulasta/Neulasta Onpro

- Udenyca

Product Name: Leukine, Neupogen, Nivestym, Releuko, or Zarxio	
Diagnosis	Human Immunodeficiency Virus (HIV)-Related Neutropenia (Off-Label)
Approval Length	6 months [11, 15, H]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is infected with HIV virus [11- 13]</p> <p style="text-align: center;">AND</p> <p>2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist/oncologist • Infectious disease specialist <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to both of the following (applies to Neupogen and Releuko only):</p> <ul style="list-style-type: none"> • 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
<p>Approval Criteria</p> <p>1 - Patient is infected with HIV virus [11- 13]</p> <p style="text-align: center;">AND</p> <p>2 - ANC less than or equal to 1,000 (cells/mm3) [12, 13]</p> <p style="text-align: center;">AND</p> <p>3 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Hematologist/oncologist • Infectious disease specialist <p style="text-align: center;">AND</p> <p>4 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure or intolerance to both of the following:</p> <ul style="list-style-type: none"> • 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
<p>Approval Criteria</p> <p>1 - One of the following:</p>	

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	<ul style="list-style-type: none"> • Dose-dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin)
Bone Cancer	<ul style="list-style-type: none"> • VAI (vincristine, doxorubicin or dactinomycin, ifosfamide) • VDC-IE (vincristine, doxorubicin or dactinomycin, and cyclophosphamide alternating with ifosfamide and etoposide) • Cisplatin/doxorubicin • VDC (cyclophosphamide, vincristine, doxorubicin or dactinomycin) • VIDE (vincristine, ifosfamide, doxorubicin or dactinomycin, etoposide)
Breast Cancer ¹⁸	<ul style="list-style-type: none"> • Dose-dense AC followed by dose-dense paclitaxel (doxorubicin, cyclophosphamide, paclitaxel) • TAX (docetaxel, doxorubicin, cyclophosphamide) • TC (docetaxel, cyclophosphamide) • TCH (docetaxel, carboplatin, trastuzumab)
Colorectal Cancer	<ul style="list-style-type: none"> • FOLFOXIRI (fluorouracil, leucovorin, oxaliplatin, irinotecan)
Head and Neck Squamous Cell Carcinoma	<ul style="list-style-type: none"> • TPF (docetaxel, cisplatin, 5-fluorouracil)
Hodgkin Lymphoma	<ul style="list-style-type: none"> • Brentuximab vedotin + AVD (doxorubicin, vinblastine, dacarbazine) • Escalated BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)
Kidney Cancer	<ul style="list-style-type: none"> • Doxorubicin/gemcitabine
Non-Hodgkin's Lymphomas	<ul style="list-style-type: none"> • Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin) • ICE (ifosfamide, carboplatin, etoposide) • Dose-dense CHOP-14 (cyclophosphamide, doxorubicin, vincristine, prednisone) • MINE (mesna, ifosfamide, mitoxantrone, etoposide) • DHAP (dexamethasone, cisplatin, cytarabine) • ESHAP (etoposide, methylprednisolone, cisplatin, cytarabine) • HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone)
Melanoma	<ul style="list-style-type: none"> • Dacarbazine-based combination with IL-2, interferon alfa (dacarbazine, cisplatin, vinblastine, IL-2, interferon alfa)
Multiple Myeloma	<ul style="list-style-type: none"> • DT-PACE (dexamethasone/thalidomide/cisplatin/doxorubicin/cyclophosphamide/etoposide) +/- bortezomib (VTD-PACE)

Ovarian Cancer	<ul style="list-style-type: none"> • Topotecan • Docetaxel
Pancreatic Cancer	<ul style="list-style-type: none"> • FOLFIRINOX (fluorouracil, leucovorin, irinotecan, oxaliplatin)
Soft Tissue Sarcoma	<ul style="list-style-type: none"> • MAID (mesna, doxorubicin, ifosfamide, dacarbazine) • Doxorubicin • Ifosfamide/doxorubicin
Small Cell Lung Cancer	<ul style="list-style-type: none"> • Topotecan
Testicular Cancer	<ul style="list-style-type: none"> • VIP (etoposide, ifosfamide, cisplatin) • VeIP (vinblastine, ifosfamide, cisplatin) • TIP (paclitaxel, ifosfamide, cisplatin)

Table 3. Examples of chemotherapy regimens with an intermediate risk of FN (10-20%) [16]

Cancer	Regimen
Occult Primary-Adenocarcinoma	<ul style="list-style-type: none"> • Gemcitabine/docetaxel
Breast Cancer	<ul style="list-style-type: none"> • Docetaxel • AC (doxorubicin, cyclophosphamide) + sequential docetaxel (adjuvant) (taxane portion only) • Paclitaxel every 21 days•
Cervical Cancer	<ul style="list-style-type: none"> • Cisplatin/topotecan • Paclitaxel/cisplatin • Topotecan • Irinotecan
Colorectal Cancer	<ul style="list-style-type: none"> • FOLFOX (fluorouracil, leucovorin, oxaliplatin)
Non-Hodgkin's Lymphomas (NHL) ²⁶	<ul style="list-style-type: none"> • GDP (gemcitabine, dexamethasone, cisplatin/carboplatin) • CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) including regimens with pegylated liposomal doxorubicin • CHP (cyclophosphamide, doxorubicin, prednisone) + brentuximab vedotin • Bendamustine
Non-Small Cell Lung Cancer	<ul style="list-style-type: none"> • Cisplatin/paclitaxel • Cisplatin/vinorelbine • Cisplatin/docetaxel

	<ul style="list-style-type: none"> • Cisplatin/etoposide • Carboplatin/paclitaxel • Docetaxel
Ovarian Cancer	<ul style="list-style-type: none"> • Carboplatin/docetaxel
Prostate Cancer	<ul style="list-style-type: none"> • Cabazitaxel
Testicular Cancer	<ul style="list-style-type: none"> • Etoposide/cisplatin • BEP (bleomycin, etoposide, cisplatin)
Esophageal and Gastric Cancer	<ul style="list-style-type: none"> • Irinotecan/cisplatin • Epirubicin/cisplatin/5-fluorouracil • Epirubicin/cisplatin/capecitabine
Small Cell Lung Cancer	<ul style="list-style-type: none"> • Etoposide/carboplatin
Uterine Cancer	<ul style="list-style-type: none"> • Docetaxel

Table 4. Examples of FDA-approved chemotherapeutic agents with dose-limiting myelosuppression

Generic Name	Brand Name
Busulfan	Busulfex [®] , Myleran [®]
Carboplatin	Paraplatin [®]
Carmustine (BCNU)	BiCNU [®] , Gliadel [®]
Chlorambucil	Leukeran [®]
Cladribine	Luestatin [®]
Cyclophosphamide	Cytoxan [®]
Cytarabine	N/A
Dacarbazine (DTIC)	DTIC-Dome [®]
Dactinomycin	Actinomycin D [®] , Cosmegen [®]
Daunorubicin	Cerubidine [®]
Daunorubicin Liposomal	DaunoXome [®]
Doxorubicin	Adriamycin PFS [®] , Adriamycin RDF [®] , Adriamycin [®]
Doxorubicin Liposomal	Doxil [®]
Etoposide	Etopophos [®] , Toposar [®] , VePesid [®]
Fluorouracil (5-FU)	Adrucil [®] , Efudex [®] , Fluoroplex [®]
Floxuridine	FUDR [®]
Fludarabine	Fludara [®]
Hydroxyurea	Droxia [®] , Hydrea [®]
Ifosfamide/Mesna	Ifex [®] , Mesnex [®]
Lomustine (CCNU)	CeeNU [®]
Mechlorethamine (Nitrogen Mustard)	Mustargen [®]
Melphalan	Alkeran [®]
Mercaptopurine (6-MP)	Purinethol [®]
Methotrexate	Rheumatrex [®] , Trexall [®]

Mitomycin	N/A
Mitoxantrone	Novantrone®
Paclitaxel	Onxol™, Taxol®
Procarbazine	Matulane®
Teniposide	Vumon®
Thioguanine (6-TG)	Tabloid®
Thiotepa	Thiotepa®
Vinblastine	N/A
Vincristine	Vincasar® PFS
Vinorelbine	Navelbine®

4 . Endnotes

- A. Currently there is no information available about the effect of longer acting pegylated G-CSF in patients with myeloid leukemias, therefore pegylated G-CSF should not be used in such patients outside of clinical trials. [17]
- B. The safety and efficacy of Leukine in AML induction or consolidation in adults younger than 55 years old have not been established in clinical trials. [3]
- C. Per hematology/oncology consultant and member of P&T, most cycles of induction or consolidation chemotherapy last ~ 1 month, but patients who complete therapy typically receive 1 induction and 2-3 consolidations, so re-approval would need to occur every month.
- D. The safety and efficacy of pegylated G-CSF has not been fully established in the setting of dose-dense chemotherapy. [17]
- E. Per hematology/oncology consultant and member of P&T, in general, dose-dense regimens require growth factor support for chemotherapy administration. [16] Also, Neulasta is commonly used to support dose dense regimens in current community practice. It would be reasonable to allow Neulasta use [in the INT C9741 Protocol] and to broaden its use for other forms of dose dense chemotherapy.
- F. The product information for both PEG-Intron and Pegasys recommends dose reduction in patients with neutropenia with an ANC level < 750 cells/mm³. [21, 22]
- G. Per GI consultant and member of P&T, his medical group of practicing hepatologists recommends Neupogen for a special subpopulation of patients with HIV infection, status post liver transplant, or established cirrhosis who experience interferon-induced neutropenia (ANC less than or equal to 500 cells/mm³) due to treatment with Peg-Intron or Pegasys.
- H. Guidelines issued by the U.S. Public Health Service (USPHS) and the Infectious Diseases Society of America (IDSA) recommend for HIV-related neutropenia, the length of therapy with G-CSF and GM-CSF is 2-4 weeks. The clinical benefit of G-CSF therapy was evaluated in a randomized, double-blind, placebo controlled trial of 30 patients evaluating G-CSF 03 mg/mL subcutaneously 3 times a week or placebo for 12 weeks. The 6 month approval duration mirrors the 6 month approval duration for the erythropoietic agents, as G-CSF has been effective when used alone or in conjunction with epoetin alfa in adults with acquired immunodeficiency syndrome (AIDS) to ameliorate the hematologic toxicity (severe anemia and/or granulocytopenia) associated with zidovudine therapy. [11, 15, 37]

- I. Note: This list is NOT inclusive of all chemotherapy regimens with a high risk of FN: See Table 2 in Background section
- J. Note: This list is NOT inclusive of all chemotherapy regimens with an intermediate risk of FN: See Table 3 in Background section
- K. Risk factors are based on provider information, not the list in the table below. Examples of risk factors may include (but are NOT limited to): Risk factors associated with chemotherapy-induced infection, FN, or neutropenia • Age > 65 years [16, 17] • History of extensive prior chemotherapy or radiation therapy including large radiation ports [16, 17] • Previous episodes of FN [16, 17] • Administration of combined chemoradiotherapy [17] • Pre-existing neutropenia or bone marrow involvement with tumor [16, 17] • Pre-existing conditions [16] • Neutropenia • Active infection/open wounds • Recent surgery • Poor performance status [16, 17] • Poor renal function [16] • Liver dysfunction [16] • Poor nutritional status [17] • More advanced cancer [17] • Hypotension and multiorgan dysfunction (Sepsis syndrome) [16, 17] • Pneumonia [16] • Invasive fungal infection [16, 17] • Other clinically documented infections [16] • Hospitalization at the time of fever [16] • Anticipated prolonged (> 10 days) and profound neutropenia (< 100/mm³) [17] • Uncontrolled primary disease [17] • Other serious comorbidities [17]
- L. Note: This list is NOT all inclusive: See Table 4 in Background section
- M. The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. [33] The American Society of Clinical Oncology states that pegfilgrastim, filgrastim, tbofilgrastim, and filgrastim-sndz (and other biosimilars as they become available) can be used for the prevention of treatment-related febrile neutropenia. The choice of agent depends on convenience, cost, and clinical situation. [34] NCCN lists FDA-approved biosimilars as appropriate substitutes for filgrastim and pegfilgrastim. Limited data suggest that patients can alternate between the biosimilar and the originator biologic without any clinically meaningful differences regarding efficacy or safety. [16]
- N. The efficacy of G-CSFs or GM-CSF for the acute radiation syndrome setting was studied in non-human primate models of radiation injury measuring 60-day survival. An expert panel convened by the World Health Organization recommends that patients receive G-CSF or GM-CSF treatment until their absolute neutrophil count reaches and maintains a level greater than 1.0 x 10⁹ cells per liter in the absence of active infection. Patients with severe hematopoietic injury may recover, either spontaneously or after G-CSF treatment alone. In most cases, a duration of two to three weeks would be expected. [1-3, 36]

5 . References

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6 . Revision History

Date	Notes
12/11/2023	Updated to include OptumRx EHB

Commercial MEDLIMIT CDUR Criteria



Prior Authorization Guideline

Guideline ID	GL-132135
Guideline Name	Commercial MEDLIMIT CDUR Criteria

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/16/2017
P&T Revision Date:	10/16/2019 ; 04/15/2020 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 10/18/2023

1 . Criteria

Product Name: Requested opioid pain medication	
Diagnosis	Level of Care Change
Approval Length	1 Time(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Provider confirms replacement prescription(s) of opioid medication(s) is needed because the patient is physically changing locations and cannot take their prescription with them [such as admission to a long term care (LTC) facility]</p>	

Product Name: Requested opioid pain medication	
Diagnosis	Pain Due to Cancer or Sickle Cell Anemia
Approval Length	12 Months to override MME edit
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Confirmation opioids are being used for the management of cancer pain or sickle cell anemia</p>	

Product Name: Requested opioid pain medication	
Diagnosis	Hospice, Long Term Care, or End-of-Life Care Enrollment
Approval Length	12 Months to override MME edit
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Patient is currently enrolled in hospice, end-of-life care, or resides in a long term care facility</p>	

Product Name: Requested opioid pain medication	
Diagnosis	Other Pain
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - A written or verbal supporting statement is received from the requesting prescriber attesting that in his/her clinical judgment, the requested dose exceeding the current cumulative morphine milligram equivalent (MME) threshold* is medically required</p>	
Notes	<p>*MME is calculated using all of the member's current opioid prescriptions</p> <p>*Note: Ask provider, "Will there be a dose escalation in the patient's o</p>

	pioid utilization in the next 90 days?" If yes, approve MME level 90 daily MME above the rejected level.
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2 . Endnotes

- A. All opioid medication edits are subject to review and modification (either to increase or decrease existing MME Limits) based on an Exception request received from the member or the member's provider. The decision to remove, modify, or retain an existing restriction on opioid pain medications will be based on evidence of new clinical information which is documented in the form of a written supporting statement received from the prescriber and which contains all of the required elements as outlined in the criteria above.

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4 . Revision History

Date	Notes
10/4/2023	Annual review: Background updates.

Compounded Drugs

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Prior Authorization Guideline

Guideline ID	GL-127732
Guideline Name	Compounded Drugs

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	8/17/2020
P&T Revision Date:	08/15/2019 ; 04/15/2020 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Criteria

Product Name: Compounded drugs**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Each active ingredient in the compounded drug is FDA-approved or national compendia* supported for the condition being treated</p> <p style="text-align: center;">AND</p>	

2 - The therapeutic amounts are supported by national compendia* or two peer-reviewed literature for the condition being treated in the requested route of delivery

AND

3 - If any prescription ingredients require prior authorization and/or step therapy, all drug-specific criteria must be also met

AND

4 - The compounded drug must not include any ingredient that has been withdrawn or removed from the market due to safety reasons (refer to Table 1)

AND

5 - The patient has tried and failed therapy or had an intolerance to two FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless one of the following criteria are met:

5.1 Patient has a contraindication to commercially available products

OR

5.2 One or no other therapeutic alternatives are commercially available

OR

5.3 Prepared in a strength not commercially available or currently in short supply

OR

5.4 Prepared in a different dosage form for a patient who is unable to take the commercially available formulation (mixing or reconstituting commercially available products based on the manufacturer's instructions or the product's approved labeling does NOT meet this criteria).

OR

5.5 Patient has an allergy or sensitivity to inactive ingredients (e.g. dyes, preservatives, sugars, etc.) that are found in commercially available products.

AND

6 - The compounded drug must not be used for a cosmetic purpose.

AND

7 - If the compound is subject to the drug-specific/targeted compound program, the member meets all the applicable drug-specific criteria below for all the targeted ingredient(s) used in the requested compound product.

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>*Approved national compendia are referenced in the "Coverage of Off-Label or Non-FDA Approved Indications" Guideline</p> <p>**Administrative guideline may not apply to all compound reviews, depending on the ingredients being used and client elections.</p>
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Product Name: Diclofenac compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include diclofenac will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p>	

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Mild to moderate pain
- Pain due to minor strains, sprains or contusions
- Migraine
- Primary dysmenorrhea
- Actinic keratosis
- Ankylosing spondylitis
- Inflammatory disorder of the eye
- Photophobia
- Pain in the eye

AND

1.3 The final dosage form will be for oral, topical, or ophthalmic use

AND

1.4 The final dosage form and strength of the diclofenac ingredient is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the diclofenac targeted compound program.</p>
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Product Name: Flurbiprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include flurbiprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 18 years of age or older

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Intraoperative miosis inhibition

AND

1.3 The final dosage form will be for oral or ophthalmic use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section. **Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the flurbiprofen targeted compound program.
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Product Name: Fluticasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include fluticasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 3 months of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis</p> <p style="text-align: center;">AND</p> <p>1.3 The final dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).</p> <p style="text-align: center;">AND</p> <p>1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)</p>	
Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>** Administrative guideline and other drug-specific guidelines may apply</p>

	y. This drug-specific criteria only applies to clients who enrolled in the fluticasone targeted compound program.
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Product Name: Gabapentin compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include gabapentin will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 3 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Patient must have one of the following diagnoses:</p> <ul style="list-style-type: none"> • Partial seizures • Postherpetic neuralgia • Restless leg syndrome (RLS) <p style="text-align: center;">AND</p> <p>1.3 The final dosage form will be for oral use</p> <p style="text-align: center;">AND</p> <p>1.4 The requested dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).</p>	

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the gabapentin targeted compound program.</p>
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Product Name: Ketamine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include ketamine will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 16 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following:</p> <p>1.2.1 Patient is requiring ketamine for conscious sedation prior to a diagnostic or surgical procedure that do not require skeletal muscle relaxation</p> <p style="text-align: center;">OR</p> <p>1.2.2 Patient is requiring ketamine for the induction of anesthesia prior to the administration of other general anesthetic agents</p> <p style="text-align: center;">OR</p> <p>1.2.3 Patient is requiring ketamine as a supplement to low-potency anesthetic agents, such as nitrous oxide</p> <p style="text-align: center;">AND</p>	

<p>1.3 The final dosage form will be for injection</p> <p style="text-align: center;">AND</p> <p>1.4 The requested dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).</p> <p style="text-align: center;">AND</p> <p>1.6 The requested dose does not exceed the concentration limit of 100mg/mL*</p>	
Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>*According to the prescribing information, 100mg/ml product must be diluted prior to administration.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the ketamine targeted compound program.</p>

Product Name: Ketoprofen compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include ketoprofen will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p>	

AND

1.2 Diagnosis of one of the following:

- Osteoarthritis
- Rheumatoid arthritis
- Acute pain
- Primary dysmenorrhea

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the ketoprofen targeted compound program.</p>
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Product Name: Levocetirizine compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
Approval Criteria	

1 - Compounded drugs that include levocetirizine will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 6 months of age or older

AND

1.2 Diagnosis of one of the following:

- Seasonal or perennial allergic rhinitis
- Uncomplicated skin manifestations of chronic idiopathic urticaria

AND

1.3 The final dosage form will be for oral use

AND

1.4 The final dose is not commercially available

AND

1.5 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the levocetirizine targeted compound program.</p>
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Product Name: Mometasone compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization

Approval Criteria

1 - Compounded drugs that include mometasone will be considered for coverage under the pharmacy benefit program when the following criteria are met:

1.1 Patient is 2 years of age or older

AND

1.2 Diagnosis of Inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses, including but not limited to atopic dermatitis, contact dermatitis, eczema, psoriasis

AND

1.3 The final dose is not commercially available

AND

1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available).

AND

1.5 The compounded product is not being used for cosmetic purposes (i.e., scar treatment, anti-aging, skin lightening, etc.)

Notes

Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.

**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the mometasone targeted compound program.

Product Name: Acyclovir ointment 5% compounds**

Approval Length	6 months, unless the provider requests for a shorter length of therapy
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include Acyclovir ointment 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Diagnosis for one of the following:</p> <ul style="list-style-type: none"> • Management of initial genital herpes • Limited non-life-threatening mucutaneous herpes simplex virus infection in immunocompromised patients <p style="text-align: center;">AND</p> <p>1.3 The final dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)</p>	
Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the Acyclovir ointment 5% targeted compound program.</p>

Product Name: Doxepin cream 5% compounds**	
Approval Length	6 months, unless the provider requests for a shorter length of therapy

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Compounded drugs that include Doxepin cream 5% will be considered for coverage under the pharmacy benefit program when the following criteria are met:</p> <p>1.1 Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>1.2 Treatment of moderate pruritus with atopic dermatitis or lichen simplex chronicus</p> <p style="text-align: center;">AND</p> <p>1.3 The final dose is not commercially available</p> <p style="text-align: center;">AND</p> <p>1.4 The patient has tried and failed therapy or had an intolerance to three FDA-approved commercially-available prescription therapeutic alternatives, one of which is the same route of administration as the requested compound, unless there is there is a reason for not using an alternative (e.g., contraindication, two or less similar products commercially-available)</p>	
Notes	<p>Compounded drugs are considered experimental/investigational for reasons not listed in this coverage policy section.</p> <p>**Administrative guideline and other drug-specific guidelines may apply. This drug-specific criteria only applies to clients who enrolled in the Doxepin cream 5% targeted compound program.</p>

2 . Background

Benefit/Coverage/Program Information
<p>Table 1: Drugs that were withdrawn from the market due to safety or effectiveness</p>

3,3',4',5-tetrachlorosalicylanilide	Methopholine Methoxyflurane
Adenosine phosphate	Methoxyflurane
Adrenal cortex	Mibefradil dihydrochloride
Alatrofloxacin mesylate	Nitrofurazone
Aminopyrine	Nomifensine maleate
Astemizole	Novobiocin
Azaribine	Ondansetron hydrochloride
Benoxaprofen	Oxyphenisatin
Bithionol	Oxyphenisatin acetate
Bromfenac sodium	Pemoline
Bromocriptine mesylate	Pergolide mesylate
Butamben	Phenacetin
Camphorated oil	Phenformin hydrochloride
Carbetapentane citrate	Phenylpropanolamine
Casein, iodinated	Pipamazine
Cerivastatin sodium	Polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride, and bisacodyl
Chloramphenicol	Potassium arsenite
Chlorhexidine gluconate	Potassium chloride
Chlormadinone acetate	Povidone
Chloroform	Propoxyphene
Cisapride	Rapacuronium bromide
Cobalt	Reserpine
Dexfenfluramine hydrochloride	

Diamthazole dihydrochloride	Rofecoxib
Dibromsalan	Sibutramine hydrochloride
Diethylstilbestrol	Sparteine sulfate
Dihydrostreptomycin sulfate	Sulfadimethoxine
Dipyron	Sulfathiazole
Encainide hydrochloride	Suprofen
Esmolol hydrochloride	Sweet spirits of nitre
Etretinate	Tegaserod maleate
Fenfluramine hydrochloride	Temafloxacin hydrochloride
Flosequinan	Terfenadine
Gatifloxacin	Tetracycline
Gelatin	Ticrynafen
Glycerol, iodinated	Tribromsalan
Gonadotropin, chorionic	Trichloroethane
Grepafloxacin	Troglitazone
Mepazine	Trovafloxacin mesylate
Metabromsalan	Urethane
Methamphetamine hydrochloride	Valdexocib
Methapyrilene	Vinyl chloride
	Zirconium
	Zomepirac sodium
Diclofenac Compounds	

There is little to no evidence-based literature support for the use of diclofenac for indications and in dosage forms not currently approved by the FDA. Use of compounds containing diclofenac should be limited to the following FDA-approved indications.

1. Diclofenac is indicated for a number of conditions including:

- Management of mild to moderate acute pain or osteoarthritis pain,
- Relief of signs and symptoms of ankylosing spondylitis and rheumatoid arthritis
- Relieve acute pain associated with minor sprains, strains, and contusions
- Treatment of primary dysmenorrhea
- Treatment of acute migraine attacks with or without aura in adults
- Treatment of actinic keratosis
- Treatment of postoperative inflammation in patients who have undergone cataract surgery and temporary relief of pain and photophobia associated with corneal refractive surgery.

2. Safety and efficacy in pediatric populations has not been established.

3. Diclofenac is commercially available in the several dosage forms: oral capsules, oral tablets, oral solution, topical patch, topical gel, topical solution, topical ointment and ophthalmic solution.

Flurbiprofen Compounds

There is little to no evidence-based literature support for the use of flurbiprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing flurbiprofen should be limited to the following FDA-approved indications.

- Flurbiprofen tablets are indicated for relief of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Flurbiprofen ophthalmic solution is indication for preventing intraoperative miosis.
- Flurbiprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Flurbiprofen is commercially available as a 50 and 100 mg oral tablet and also as 0.03% sterile ophthalmic solution.

Fluticasone Compounds

There is little to no evidence-based literature support for the use of fluticasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing fluticasone should be limited to the following FDA-approved indications.

- Fluticasone cream indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 3 months of age or older.

Fluticasone is commercially available in the several dosage forms: topical cream, topical lotion, topical ointment, nasal spray and various aerosols and powders for inhalation

Gabapentin Compounds

There is little to no evidence-based literature support for the use of gabapentin for indications or in dosage forms not currently approved by the FDA. Use of compounds containing gabapentin should be limited to the following FDA-approved indications.

- Gabapentin is indicated for treatment postherpetic neuralgia in adults (Gralise prescribing information, 2012; Horizant prescribing information, 2013; Neurontin prescribing information, 2015).
- Gabapentin is indicated as adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalization, in adults and pediatric patients 3 years and older with epilepsy (Neurontin prescribing information, 2015).
- Gabapentin is indicated for the treatment of moderate to severe primary restless leg syndrome (Horizant prescribing information, 2013).

Ketamine Compounds

There is little to no evidence-based literature support for the use of ketamine for indications or in dosage forms not currently approved by the FDA. Use of compounds containing ketamine should be limited to the following FDA-approved indications.

- Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation (Ketalar prescribing information, 2016)
- Ketamine is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents (Ketalar prescribing information, 2016)
- Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (Ketalar prescribing information, 2016)
- Esketamine (the S-enantiomer of racemic ketamine) is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults (Spravato prescribing information, 2019). Coverage of compounds with racemic ketamine will continue to be limited to the FDA approved indications listed above.

Ketoprofen Compounds

There is little to no evidence-based literature support for the use of ketoprofen for indications and in dosage forms not currently approved by the FDA. Use of compounds containing ketoprofen should be limited to the following FDA-approved indications.

- Ketoprofen immediate-release capsules and ketoprofen extended-release capsules are indicated for the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis.
- Ketoprofen immediate-release capsules are indicated for the management of pain and for treatment of primary dysmenorrhea.
- Ketoprofen extended-release capsules are not recommended for treatment of acute pain because of its extended-release characteristics.
- Ketoprofen as a topically compounded formulation has not been shown to be more effective than currently commercially available topical NSAID products.
- Ketoprofen is commercially available as a 50 and 75 mg oral capsule and 200 mg extended release oral capsule.

Levocetirizine Compounds

There is little to no evidence-based literature support for the use of levocetirizine for indications and in dosage forms not currently approved by the FDA. Use of compounds containing levocetirizine should be limited to the following FDA-approved indications.

- Levocetirizine dihydrochloride, a histamine (H₁) receptor antagonist, is indicated for:
 - Treatment of perennial allergic rhinitis in adults and children 6 months of age or older.
 - Treatment of seasonal allergic rhinitis in adults and children 2 years of age and older
 - Uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older
- Levocetirizine is commercially available as a 5 mg oral tablet and 2.5 mg/mL oral solution.

Mometasone Compounds

There is little to no evidence-based literature support for the use of mometasone for indications and in dosage forms not currently approved by the FDA. Use of compounds containing mometasone should be limited to the following FDA-approved indications.

- Mometasone cream & ointment are indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 2 years of age.
- Mometasone lotion is indicated for the treatment of relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patient's ≥ 12 years of age.

- Mometasone is commercially available in several dosage forms: topical cream, topical lotion, topical ointment, nasal spray, powder for inhalation and sinus implant.

Acyclovir ointment 5% Compounds

There is little to no evidence-based literature support for the use of Acyclovir ointment 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Acyclovir ointment 5% should be limited to the following FDA-approved indications.

- Acyclovir ointment 5% is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infection in immunocompromised patients.
- Acyclovir is commercially available in several dosage forms: topical ointment, topical cream, buccal tablet, tablet, capsule, oral suspension, and intravenous solution.

Doxepin cream 5% Compounds

There is little to no evidence-based literature support for the use of Doxepin cream 5% for indications and in dosage forms not currently approved by the FDA. Use of compounds containing Doxepin cream 5% should be limited to the following FDA-approved indications.

- Doxepin cream 5% is indicated for short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus.
- Doxepin cream 5% is commercially available in several dosage forms: topical cream, capsule, tablet, and oral concentrate

3 . Endnotes

- A. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. [1]
- B. Compound drugs are customized in the following ways to meet patients need: (1) Removal of a nonessential ingredient for patients' allergies; and (2) Change in medication formulation (e.g., pill to solution in a patient with swallowing difficulties). [1]
- C. Benefit design recommendations provided in the OptumRx Commercial Implementation Guide: (1) \$200 Rx High Dollar Limit at Retail; (2) The processing of compound drugs will be subject to the same benefit plan edits: day supply, copay and drug coverage; (3) Multiple ingredient processing is recommended; (4) Bulk chemicals and compound kit recommended as standard exclusions.
- D. Compounding does not generally include mixing or reconstituting commercially available products in accordance with the manufacturer's instructions or the product's approved labeling.

4 . References

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5 . Revision History

Date	Notes
7/7/2023	2023 Annual Review. No changes to criteria.

Constipation Agents

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Prior Authorization Guideline

Guideline ID	GL-135334
Guideline Name	Constipation Agents

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/18/2008
P&T Revision Date:	5/18/2023

1 . Indications

Drug Name: Amitiza (lubiprostone)
<p>Chronic Idiopathic Constipation (CIC) Indicated for the treatment of CIC in adults.</p> <p>Opioid-Induced Constipation in Adult Patients with Chronic Non-Cancer Pain Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation. Limitations of Use: Effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane opioids (e.g., methadone) has not been established.</p> <p>Irritable Bowel Syndrome with Constipation Indicated for the treatment of irritable bowel syndrome with constipation in women at least 18 years old.</p>
Drug Name: Linzess (linaclotide)
<p>Irritable Bowel Syndrome with Constipation (IBS-C) Indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C).</p> <p>CIC Indicated in adults for the treatment of CIC.</p>

Functional Constipation (FC) Indicated in pediatric patients 6 to 17 years of age for the treatment of functional constipation (FC).

Drug Name: Movantik (naloxegol)

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Motegrity (prucalopride)

CIC Indicated for the treatment of CIC in adults.

Drug Name: Relistor (methylnaltrexone bromide) injection

Opioid-Induced Constipation (advanced illness or pain caused by active cancer) [1, 2] Indicated for the treatment of OIC in adult patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Relistor (methylnaltrexone bromide) tablet

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Symproic (naldemedine)

Opioid-Induced Constipation (chronic non-cancer pain, chronic pain related to prior cancer or its treatment) Indicated for the treatment of OIC in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

Drug Name: Trulance (plecanatide)

CIC Indicated in adults for the treatment of CIC.

IBS-C Indicated in adults for the treatment of IBS-C.

2 . Criteria

Product Name: Brand Amitiza	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]</p> <ul style="list-style-type: none"> • Lactulose • Polyethylene glycol <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]</p> <ul style="list-style-type: none"> • Linzess • Movantik • Symproic 	

Product Name: Linzess, Movantik, Symproic	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p>	

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

Product Name: Motegrity, Trulance

Approval Length	12 month(s)
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Guideline Type	Step Therapy
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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 days supply), contraindication, or intolerance to one of the following generics: [A]

- Lactulose
- Polyethylene glycol

AND

3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to Linzess

Product Name: Relistor injection, Relistor tablet

Approval Length	12 month(s)
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Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following generics: [A]</p> <ul style="list-style-type: none">• Lactulose• Polyethylene glycol <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to one of the following preferred brands: [B]</p> <ul style="list-style-type: none">• Movantik• Symproic	

3 . Endnotes

- A. Stimulant and osmotic laxatives should be tried/failed first before patients are placed on OIC agents (ie, Relistor and Movantik). [2, 3]
- B. The 2019 American Gastroenterological Association (AGA) Guideline for Opioid-Induced Constipation (OIC) recommends traditional laxative therapy as first-line agents given their established efficacy, safety, and lower cost. If an adequate trial of laxatives does not optimally control symptoms, the AGA recommends treatment with peripherally acting mu-opioid receptor antagonist (PAMORA) drugs with higher quality evidence of efficacy, namely naldemedine and naloxegol. [2]

4 . References

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6. Linzess Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2023.
7. Trulance Prescribing Information. Salix Pharmaceuticals Inc. Bridgewater, NJ. April 2021.
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5 . Revision History

Date	Notes
10/23/2023	Created EHB specific GL

Continuous Glucose Monitors, Sensors, and Transmitters - PA, NF



Prior Authorization Guideline

Guideline ID	GL-136301
Guideline Name	Continuous Glucose Monitors, Sensors, and Transmitters - PA, NF

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	05/19/2022 ; 09/21/2022 ; 09/21/2022 ; 02/16/2023 ; 04/19/2023 ; 06/21/2023 ; 07/19/2023 ; 12/13/2023

1 . Criteria

Product Name: Dexcom Products*, Freestyle Libre Products*	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria 1 - ALL of the following: 1.1 Diagnosis of diabetes mellitus	

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

Notes	*If patient meets criteria above, please approve all CGM components at NDC list "PREFCGMPA"
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Product Name: Dexcom Products*, Freestyle Libre Products*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - ONE of the following:</p> <p>1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:</p>	

<ul style="list-style-type: none"> • Improvement in glycemic control (e.g., lower and/or maintain A1C levels) • Reduction or improvement in hypoglycemic events <p style="text-align: center;">OR</p> <p>1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan</p>	
Notes	*If patient meets criteria above, please approve all CGM components at NDC list "PREFCGMPA"

Product Name: All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support</p> <p style="text-align: center;">AND</p> <p>1.3 ONE of the following:</p> <p>1.3.1 Patient is being treated with insulin</p> <p style="text-align: center;">OR</p>	

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Minimum 90 day trial within the last 180 days, to both of the following:

- Dexcom Products
- Freestyle Products

Notes	*If patient meets criteria above, please approve all CGM components at GPI list "CGMPA"
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Product Name: All Other Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - ONE of the following:</p> <p>1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:</p> <ul style="list-style-type: none"> • Improvement in glycemic control (e.g., lower and/or maintain A1C levels) • Reduction or improvement in hypoglycemic events <p style="text-align: center;">OR</p> <p>1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan</p>	

AND	
<p>2 - Minimum 90 day trial within the last 180 days, to both of the following:</p> <ul style="list-style-type: none"> • Dexcom Products • Freestyle Products 	
Notes	*If patient meets criteria above, please approve all CGM components at GPI list “CGMPA”

Product Name: Continuous Glucose Monitors, Sensors, and Transmitters*	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support</p> <p style="text-align: center;">AND</p> <p>1.3 ONE of the following:</p> <p>1.3.1 Submission of medical records (e.g., chart notes) or paid claims confirming patient is being treated with insulin</p> <p style="text-align: center;">OR</p>	

1.3.2 Submission of medical records (e.g., chart notes) confirming patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Submission of medical records (e.g., chart notes) or paid claims confirming minimum 90 day trial within the last 180 days, to Dexcom products

Notes	*If patient meets criteria above, please approve all CGM components at GPI list "CGMPA"
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Product Name: Bigfoot Unity Program Kit	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - ALL of the following:</p> <p>1.1 Diagnosis of diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support</p> <p style="text-align: center;">AND</p> <p>1.3 ONE of the following:</p>	

1.3.1 Patient is being treated with insulin

OR

1.3.2 Patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Minimum 90 day trial within the last 180 days to ALL of the following:

- Dexcom Products
- Freestyle Products
- Medtronic Products

Product Name: Bigfoot Unity Program Kit	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - ONE of the following:</p> <p>1.1 Patient demonstrates positive clinical response as evidenced by ONE of the following:</p> <ul style="list-style-type: none"> • Improvement in glycemic control (e.g., lower and/or maintain A1C levels) • Reduction or improvement in hypoglycemic events <p style="text-align: center;">OR</p>	

1.2 Patient is being assessed by the prescriber for adherence to their CGM regimen and diabetes treatment plan

Product Name: Bigfoot Unity Program Kit

Approval Length | 12 month(s)

Guideline Type | Non Formulary

Approval Criteria

1 - ALL of the following:

1.1 Diagnosis of diabetes mellitus

AND

1.2 Patient is adherent to current diabetes treatment plan and participates in ongoing diabetes education and support

AND

1.3 ONE of the following:

1.3.1 Submission of medical records (e.g., chart notes) or paid claims confirming patient is being treated with insulin

OR

1.3.2 Submission of medical records (e.g., chart notes) confirming patient has a history of problematic hypoglycemia with at least one of the following:

- Recurrent (more than one) level 2 hypoglycemic events (glucose less than 54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan
- Patient has a history of one level 3 hypoglycemic event (glucose less than 54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia

AND

1.4 Submission of medical records (e.g., chart notes) or paid claims confirming minimum 90 day trial within the last 180 days to ALL of the following:

- Dexcom Products
- Freestyle Products
- Medtronic Products

2 . Endnotes

- A. People who have been using continuous glucose monitoring, continuous subcutaneous insulin infusion, and/or automated insulin delivery for diabetes management should have continued access across third party payers. Interruption of access to CGM is associated with a worsening of outcomes, therefore, it is important for individuals on CGM to have consistent access. [2]

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3. BigFoot Unity PDF. Available at: <https://f.hubspotusercontent40.net/hubfs/5085144/PDFs/Bigfoot%20Unity%E2%84%A2%20System%20User%20Guide.pdf>. Accessed May 23, 2023.

4 . Revision History

Date	Notes
12/14/2023	update guideline

Contraceptives for Non-Contraceptive Use

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Prior Authorization Guideline

Guideline ID	GL-129283
Guideline Name	Contraceptives for Non-Contraceptive Use

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	12/6/2004
P&T Revision Date:	07/15/2020 ; 07/15/2020 ; 07/15/2020 ; 02/18/2021 ; 07/21/2021 ; 08/18/2022 ; 8/17/2023

Note:

This guideline applies to grandfathered plans (i.e., plans with a separate contraceptive account or CSO) when the contraceptive is not being used for contraception purposes. This guideline is also used for members without HCR Contraceptive or Family Planning Benefits.

1 . Criteria

Product Name: Formulary and Non Formulary Contraceptives	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - Patient is using the medication for non-contraception purposes*	
Notes	*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraine s; (16) Turner’s syndrome; (17) Uterine fibroids or adenomyosis. [1-7, 9-12]

2 . Background

Clinical Practice Guidelines

Table 1. Contraceptives [3, 8]

This information should not be considered comprehensive. Please refer to individual prescribing information for more details.

MONOPHASIC		
Product	Estrogen (MCG)	Progestin (MG)
Necon 1/50	50 mestranol	1 norethindrone
Norinyl 1/50		
Zovia 1/50E	50 ethinyl estradiol	1 ethynodiol diacetate
Ogestrel 0.5/50		0.5 norgestrel
Norgestimate/Ethinyl estradiol	35 ethinyl estradiol	0.25 norgestimate
Estarilla		
MonoNessa		
Ortho Cyclen-28		
Previfem		

Sprintec				
Alyacen 1/35	35 ethinyl estradiol	1 norethindrone		
Cyclafem 1/35				
Dasetta 1/35				
Necon 1/35				
Norinyl 1/35				
Nortrel 1/35				
Ortho-Novum 1/35				
Pirmella 1/35				
Brevicon			35 ethinyl estradiol	0.5 norethindrone
Modicon				
Necon 0.5/35				
Nortrel 0.5/35				
Wera				
Balziva	35 ethinyl estradiol	0.4 norethindrone		
Briellyn				
Femcon FE				
Gildagia				
Ovcon-35				
Philith				
Vyfemia				
Wymzya FE				
Zenchent				
Zenchent FE				
Kelnor 1/35			35 ethinyl estradiol	1 ethynodiol diacetate
Zovia 1/35E				
Ortho Evra	35 ethinyl estradiol	0.2 norelgestromin		
Drospirenone/Ethinyl estradiol	30 ethinyl estradiol	3 drospirenone		

Ocella		
Safyral		
Syeda		
Yasmin		
Zarah		
Desogestrel/Ethinyl estradiol		
Apri		
Desogen		
Emoquette	30 ethinyl estradiol	0.15 desogestrel
Ortho-Cept		
Reclipsen		
Solia		
Levonorgestrel/Ethinyl estradiol		
Altavera		
Chateal		
Kurvelo	30 ethinyl estradiol	0.15 levonorgestrel
Levora		
Marlissa		
Portia		
Cryselle		
Elinest	30 ethinyl estradiol	0.3 norgestrel
Low-Ogestrel		
Gildess 1.5/30	30 ethinyl estradiol	1.5 norethindrone

Gildess Fe 1.5/30		
Junel 21 Day 1.5/30		
Junel Fe 1.5/30		
Larin Fe 1.5/30		
Loestrin 1.5/30-21		
Loestrin Fe 1.5/30		
Lomedia 24 fe		
Microgestin 1.5/30		
Microgestin Fe 1.5/30		
Generess Fe	25 ethinyl estradiol	0.8 norethindrone
Gildess 1/20		
Gildess Fe 1/20		
Junel 21 Day 1/20		
Junel Fe 1/20		
Loestrin 1/20-21	20 ethinyl estradiol	1 norethindrone
Loestrin Fe 1/20		
Microgestin 1/20		
Microgestin Fe 1/20		
Levonorgestrel/Ethinyl estradiol		
Aviane		
Falmina		
Lessina	20 ethinyl estradiol	0.1 levonorgestrel
Lutera		
Orsythia		
Sronyx		
NuvaRing	15 ethinyl estradiol	0.12 etonogestrel
BIPHASIC		

Product	Estrogen (MCG)	Progestin (MG)
Azurette	20 ethinyl estradiol x 21d, placebo x 2d, 10 x 5d	0.15 desogestrel x 21d
Kariva		
Mircette		
Viorele		
Necon 10/11	35 ethinyl estradiol	0.5 norethindrone x 10d, 1 x 11d
TRIPHASIC		
Product	Estrogen (MCG)	Progestin (MG)
Estrostep Fe	20 ethinyl estradiol x 5d, 30 x 7d, 35 x 9d	1 norethindrone x 21d
Tilia Fe		
Tri-Legest Fe		
Ortho Tri-Cyclen Lo	25 ethinyl estradiol x 21d	0.18 norgestimate x 7d, 0.215 x 7d, 0.25 x 7d
Caziant	25 ethinyl estradiol x 21d	0.1 desogestrel x 7d, 0.125 x 7d, 0.15 x 7d
Cesia		
Cyclessa		
Velivet		
Enpresse	30 ethinyl estradiol x 6d, 40 x 5d, 30 x 10d	0.05 levonorgestrel x 6d, 0.075 x 5d, 0.125 x 10d
Levonest		
Myzilra		
Trivora		
Norgestimate/Ethinyl estradiol	35 ethinyl estradiol x 21d	0.18 norgestimate x 7d, 0.215 x 7d, 0.25 x 7d
Ortho Tri-Cyclen		

Tri-Estarylla		
Tri-Linyah		
Trinessa		
Tri-Previfem		
Tri-Sprintec		
Aranelle		
Leena	35 ethinyl estradiol x 21d	0.5 norethindrone x 7d, 1 x 9d, 0.5 x 5d
Tri-Norinyl		
Alyacen 7/7/7		
Cyclafem 7/7/7		
Dasetta 7/7/7		
Necon 7/7/7	35 ethinyl estradiol x 21d	0.5 norethindrone x 7d, 0.75 x 7d, 1 x 7d
Nortrel 7/7/7		
Ortho-Novum 7/7/7		
Pirmella 7/7/7		
FOUR-PHASIC		
Product	Estrogen (MG)	Progestin (MG)
Natazia	3 estradiol valerate x 2d, 2 x 22d, 1 x 2d, 0 x 2d	0 dienogest x 2d, 2 x 5d, 3 x 17d, 0 x 4d
EXTENDED-/CONTINUOUS-CYCLE		
Product	Estrogen (MCG)	Progestin (MG)
Lo Loestrin Fe	10 ethinyl estradiol x 26d	1 norethindrone x 24d
Lo Minastrin Fe		
Loestrin-24 FE	20 ethinyl estradiol x 24d	1 norethindrone x 24d
Minastrin 24 Fe		
Levonorgestrel/Ethinyl estradiol	20 ethinyl estradiol x 84d, 10 x 7d	0.1 levonorgestrel x 84d
Amethia Lo		

Camrese Lo		
LoSeasonique		
Levonorgestrel/Ethinyl estradiol	30 ethinyl estradiol x 84d	0.15 levonorgestrel x 84d
Introvale		
Jolessa		
Quasense		
Amethia		
Camrese	30 ethinyl estradiol x 84d, 10 x 7d	0.15 levonorgestrel x 84d
Daysee		
Seasonique		
Quartette	20 ethinyl estradiol x 42d, 25 x 21d, 30 x 21d, 10 x 7d	0.15 levonorgestrel x 84d
Beyaz	20 ethinyl estradiol x 24d	3 drospirenone x 24d
Gianvi		
Loryna		
Vestura		
Yaz		
Amethyst	20 ethinyl estradiol	0.09 levonorgestrel
PROGESTIN-ONLY		
Product	Estrogen (MCG)	Progestin (MG)
Camila	N/A	0.35 norethindrone
Errin		
Heather		
Jencycla		
Jolivette		
Lyza		
Nora-BE		

Norethindrone		
Norlyroc		
Nor-QD		
Ortho-Micronor		

3 . References

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4 . Revision History

Date	Notes
8/2/2023	2023 Annual Review. No criteria changes.

Corlanor (ivabradine)



Prior Authorization Guideline

Guideline ID	GL-134050
Guideline Name	Corlanor (ivabradine)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	7/14/2015
P&T Revision Date:	08/15/2019 ; 01/15/2020 ; 08/13/2020 ; 08/19/2021 ; 08/18/2022 ; 8/18/2022

1 . Indications

Drug Name: Corlanor (ivabradine)
<p>Chronic Heart Failure Indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic, chronic heart failure with left ventricular ejection fraction less than or equal to 35%, who are in sinus rhythm with a resting heart rate greater than or equal to 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.</p> <p>Heart Failure due to Dilated Cardiomyopathy (DCM) Indicated for the treatment of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate.</p> <p>Off Label Uses: Inappropriate Sinus Tachycardia (IST) Has been used for the treatment of inappropriate sinus tachycardia (IST). [7]</p>

2 . Criteria

Product Name: Corlanor	
Diagnosis	Chronic Heart Failure
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic heart failure [3, 5]</p> <p style="text-align: center;">AND</p> <p>2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [3, 5, A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a left ventricular ejection fraction of less than or equal to 35% [3, 5]</p> <p style="text-align: center;">AND</p> <p>4 - Patient is in sinus rhythm [3, 5]</p> <p style="text-align: center;">AND</p> <p>5 - Patient has a resting heart rate that is greater than or equal to 70 beats per minute [3, 5, E]</p> <p style="text-align: center;">AND</p> <p>6 - Trial and failure, contraindication, or intolerance to all of the following at a maximally tolerated dose: [10]</p> <p>6.1 One of the following:</p>	

- Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
- Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)
- Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)]

AND

6.2 One of the following: [3, 5, 10, B-F]

- bisoprolol
- carvedilol
- metoprolol succinate extended-release

AND

6.3 Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)]

AND

6.4 Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]

AND

7 - Patient has been hospitalized for worsening heart failure in the previous 12 months [3]

AND

8 - Prescribed by or in consultation with a cardiologist

Product Name: Corlanor	
Diagnosis	Heart Failure due to Dilated Cardiomyopathy
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of heart failure due to dilated cardiomyopathy</p> <p style="text-align: center;">AND</p> <p>2 - Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms [6]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is in sinus rhythm</p> <p style="text-align: center;">AND</p> <p>4 - Patient has an elevated heart rate</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure, contraindication, or intolerance to one of the following: [1, 4, 6]</p> <ul style="list-style-type: none"> • Beta blocker (e.g., bisoprolol, metoprolol succinate extended release) • Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril) • Diuretic Agent (e.g., spironolactone, furosemide) <p style="text-align: center;">AND</p> <p>6 - Prescribed by or in consultation with a cardiologist</p>	

Product Name: Corlanor	
Diagnosis	Inappropriate Sinus Tachycardia (IST) [off-label]
Approval Length	6 month(s)

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of inappropriate sinus tachycardia (IST) confirmed by both of the following: [7]</p> <ul style="list-style-type: none"> • Sinus heart rate greater than 100 beats per minute at rest • A mean 24 hour heart rate greater than 90 beats per minute <p style="text-align: center;">AND</p> <p>2 - Documentation that other causes of sinus tachycardia have been ruled out (e.g., hyperthyroidism, anemia, illicit stimulant drug use, caffeine, etc.) [7]</p> <p style="text-align: center;">AND</p> <p>3 - Documentation that symptoms of IST are causing significant functional impairment or distress (e.g., palpitations, light-headedness, syncope, chest pain, dyspnea, etc.) [8, 9]</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with a cardiologist</p>	

Product Name: Corlanor	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

3 . Endnotes

- A. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, patients' heart failure was defined as New York Heart Association class II, III or IV [1, 3]
- B. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons for not achieving guideline-recommended doses of beta-blocker therapy were hypotension, fatigue, dyspnea, dizziness, history of cardiac decompensation, and bradycardia [1, 3]
- C. In the pivotal trial evaluating the efficacy of Corlanor in patients with heart failure, the main reasons that patients were unable to receive beta-blocker therapy were due to a diagnosis of chronic obstructive pulmonary disease, hypotension or asthma [1, 3]
- D. The following are examples of contraindications to beta-blocker therapy but is not a comprehensive list: severe bradycardia, decompensated cardiac failure, cardiogenic shock, second-or-third degree heart block, sick sinus syndrome (without a functional permanent pacemaker) [4]
- E. Corlanor slows the heart rate by inhibiting the cardiac pacemaker. If current and therefore heart rate should be at or above 70 beats per minute prior to initiation of therapy to ensure bradycardia does not ensue following initiation of therapy with Corlanor [2]
- F. Per 2022 AHA/ACC/HFSA guideline for the management of Heart Failure, three beta blockers have been shown to be effective in reducing the risk of death in patients with HFrEF: bisoprolol, metoprolol succinate, and carvedilol. [10]

4 . References

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8. Cappato R, Castelvechio S, Ricci C, et al. Clinical efficacy of ivabradine in patients with inappropriate sinus tachycardia: a prospective, randomized, placebo-controlled, double-blind, crossover evaluation. J Am Coll Cardiol. 2012 Oct 9;60(15):1323-9.
9. Sheldon RS, Grubb BP 2nd, Olshansky B, et al. 2015 heart rhythm society expert consensus statement on the diagnosis and treatment of postural tachycardia syndrome, inappropriate sinus tachycardia, and vasovagal syncope. Heart Rhythm. 2015 Jun;12(6):e41-63.
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5 . Revision History

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

Coverage of Off-Label Non-FDA Approved Indications



Prior Authorization Guideline

Guideline ID	GL-133340
Guideline Name	Coverage of Off-Label Non-FDA Approved Indications

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/2/2007
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or non-FDA approved indication	
Diagnosis	Off-label non-cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]</p>	

OR

1.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes	Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.
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Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Diagnosis	Off-label cancer indication
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis is supported as a use in AHFS DI [2]</p> <p>OR</p> <p>1.2 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section) [2, A]</p>	

OR

1.3 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of Class I, Class IIa, or Class IIb (see DRUGDEX Strength of Recommendation table in Background section) [2]

OR

1.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, B]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine

<ul style="list-style-type: none"> Radiation Oncology <p style="text-align: center;">OR</p> <p>1.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]</p>	
Notes	Off-label use may be reviewed for medical necessity and denied as such if the off-label criteria are not met. Please refer to drug specific PA guideline for off-label criteria if available.

2 . Background

Clinical Practice Guidelines		
DRUGDEX Strength of Recommendation [6]		
Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test or treatment is not useful, and should be avoided

Class Indeterminate	Evidence Inconclusive	
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NCCN Categories of Evidence and Consensus [A]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may

	<p>be necessary to further define the role of this medication for the off-label use.</p>
<p>Against proposed off-label use</p>	<p>The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.</p>

Level of Evidence Scale for Oncology Off-Label Use

<p>A</p>	<p>Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.</p>
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B	Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

3 . Endnotes

A. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a

major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]

- B. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

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5 . Revision History

Date	Notes
11/1/2023	Annual review: Background updates.

Daliresp (roflumilast)



Prior Authorization Guideline

Guideline ID	GL-137678
Guideline Name	Daliresp (roflumilast)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/16/2011
P&T Revision Date:	08/15/2019 ; 09/16/2020 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 12/14/2022 ; 01/18/2023 ; 09/20/2023 ; 9/20/2023

1 . Indications

Drug Name: Daliresp (roflumilast)
Chronic obstructive pulmonary disorder (COPD) Indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Limitations of Use: Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

2 . Criteria

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic obstructive pulmonary disease (COPD) [A, B]</p> <p style="text-align: center;">AND</p> <p>2 - History of COPD exacerbations which require the use of systemic corticosteroids, antibiotics, or hospital admission [C]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g. Combivent, Spiriva)</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)</p>	
Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Product Name: Brand Daliresp, generic roflumilast	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p> <p style="text-align: center;">AND</p>	

2 - Trial and failure or intolerance to generic roflumilast (Applies to brand Daliresp only)	
Notes	Daliresp 250 mcg is a starting dose, for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

3 . Endnotes

- A. Patients enrolled in the pivotal trials had a forced expiratory volume in 1 second [FEV1] less than or equal to 50% of predicted and FEV1/forced vital capacity [FVC] less than 0.7). [1-3]
- B. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) treatment guidelines, moderate COPD is defined as FEV1 less than 80% but greater than or equal to 50%; severe COPD is defined as FEV1 less than 50% but greater than or equal to 30%; and very severe COPD is defined as FEV1 less than 30%. [4]
- C. In the pivotal studies the rate of moderate exacerbations was defined as requiring intervention with systemic glucocorticosteroids. Severe exacerbations were defined as leading to hospitalization and/or to death. [1]

4 . References

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5 . Revision History

Date	Notes
12/12/2023	Program update to standard reauthorization language. No changes to clinical intent.

DAW Override

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Prior Authorization Guideline

Guideline ID	GL-133347
Guideline Name	DAW Override

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	12/19/2015
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a dispense as written (DAW) override program. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available.

1 . Criteria

Product Name: Brand drugs with two or more generic equivalents available	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - Patient has tried two generic equivalents of the requested drug from different manufacturers

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

Product Name: Brand drugs with only one generic equivalent available

Approval Length	12 month(s)
Guideline Type	Administrative

Approval Criteria

1 - Patient has tried one generic equivalent of the requested drug from a different manufacturer

AND

2 - One of the following:

2.1 Patient has had an allergic reaction or intolerance to an inactive ingredient

OR

2.2 Patient has experienced an inadequate response to the generic equivalent of the requested drug

AND

3 - One of the following:

3.1 Requested drug is FDA-approved for the condition being treated

OR

3.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

2 . Endnotes

- A. The standard DAW (brand name) override criteria are for clients who opt for such a program to help manage prescription costs. The criteria is applied when a provider/patient requests for coverage of a brand medication when a generic is available. There must be a clinical reason why the patient cannot take the generic version of the medication. Acceptable clinical reasons include having an inadequate response, an allergic reaction, or intolerance to two generic manufacturers of the branded product (or one if only one generic equivalent is available). Intolerance of the generic version may occur due to excipients in the generic version of the product. In order to receive approval for the prescribed drug, the prescriber will document the clinical reason as to why the patient cannot use a generic version of the product.

3 . Revision History

Date	Notes
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Deferasirox products



Prior Authorization Guideline

Guideline ID	GL-106653
Guideline Name	Deferasirox products

Guideline Note:

Effective Date:	7/1/2022
P&T Approval Date:	5/20/2015
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 07/15/2020 ; 09/16/2020 ; 05/20/2021 ; 5/19/2022

1 . Indications

<p>Drug Name: Exjade (deferiasirox), deferiasirox tablet, Jadenu (deferiasirox), Jadenu Sprinkle (deferiasirox)</p>
<p>Chronic Iron Overload Due to Blood Transfusions (Transfusional Iron Overload) Indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in patients 2 years of age and older. Limitations of Use: The safety and efficacy of deferiasirox when administered with other iron chelation therapy have not been established.</p>
<p>Treatment of Chronic Iron Overload in Non-Transfusion-Dependent Thalassemia Syndromes Indicated for the treatment of chronic iron overload in patients 10 years of age and older with non-transfusion-dependent thalassemia (NTDT) syndromes and with a liver iron concentration (LIC) of at least 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) and a serum ferritin greater than 300 mcg/L. Limitations of Use: The safety and efficacy of deferiasirox when administered with other iron chelation therapy have not been established.</p>
<p>Off Label Uses: Myelodysplastic syndrome (MDS) Low to intermediate risk myelodysplastic syndrome (MDS) for management of iron overload and in potential transplant patients who have received more than 20 red blood cell transfusions [11]</p>

2 . Criteria

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a baseline ferritin level more than 1,000 mcg/L</p> <p style="text-align: center;">AND</p> <p>4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure of generic deferasirox</p>	

Product Name: Generic deferasirox

Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 2 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a baseline ferritin level more than 1,000 mcg/L</p> <p style="text-align: center;">AND</p> <p>4 - Patient has required the transfusion of at least 100 mL/kg packed red blood cells</p>	

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic syndrome</p>	

AND
2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient
AND
3 - Patient has received more than 20 red blood cell transfusions
AND
4 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of myelodysplastic syndrome</p> <p style="text-align: center;">AND</p> <p>2 - Patient has Low or Intermediate-1 disease or is a potential transplant patient</p> <p style="text-align: center;">AND</p> <p>3 - Patient has received more than 20 red blood cell transfusions</p>	

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade
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Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of generic deferasirox</p>	

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to blood transfusions (transfusional hemosiderosis) & Myelodysplastic syndrome (MDS) [off-label]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p>	

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)

AND

2 - Patient is 10 years of age or older

AND

3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher

AND

4 - Serum ferritin level greater than 300 mcg/L

AND

5 - Trial and failure of generic deferasirox

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	
1 - Diagnosis of chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)	

AND
2 - Patient is 10 years of age or older
AND
3 - Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher
AND
4 - Serum ferritin level greater than 300 mcg/L

Product Name: Brand Jadenu, Brand Jadenu Sprinkle, Brand Exjade	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher</p> <p style="text-align: center;">AND</p> <p>2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure of generic deferasirox</p>	

Product Name: Generic deferasirox	
Diagnosis	Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has liver iron concentration (LIC) 3 mg Fe/g dw or higher</p> <p style="text-align: center;">AND</p> <p>2 - Patient experienced a reduction, from baseline, in serum ferritin level or liver iron concentration (LIC)</p>	

3 . References

1. Exjade Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. Cappellini MD, Cohen A, Piga A, et al. A Phase III study of deferasirox (ICL670), a once-daily oral iron chelator, in patients with [beta]-thalassemia. *Blood*. 2006;107(9):3455-62.
3. Cappellini MD. Iron-chelating therapy with the new oral agent ICL670 (Exjade). *Best Pract Res Clin Haematol*. 2005;18(2):289-98.
4. Galanello R, Piga A, Alberti D, Rouan MC, Bigler H, Sechaud R. Safety, tolerability, and pharmacokinetics of ICL670, a new orally active iron-chelating agent in patients with transfusion-dependent iron overload due to beta-thalassemia. *J Clin Pharmacol*. 2003;43(6):565-72.
5. Nisbet-Brown E, Olivieri NF, Giardina PJ, et al. Effectiveness and safety of ICL670 in iron-loaded patients with thalassaemia: a randomized, double-blind, placebo-controlled, dose-escalation trial. *Lancet*. 2003;361(9369):1597-602.
6. International Association of Sickle Cell Nurses and Physician Assistants. *Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload*. 2008. http://www.iascnapa.org/guidelines/Guidelines_IronOverload.pdf. Accessed on April 8, 2021.
7. Ho PJ, Tay L, Linderman R, Catley L, Bowden DK. Australian guidelines for the assessment of iron overload and iron chelation in transfusion-dependent thalassaemia major, sickle cell disease and other congenital anaemias. *Intern Med J*. 2011;41(7):516-24.

8. Angelucci E, Barosi G, Camaschella C, et al. Italian Society of Hematology practice guidelines for the management of iron overload in thalassemia major and related disorders. *Haematologica*. 2008;93(5):741-52.
9. Porter JB and Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. 2010 Dec;24(6):1109-30.
10. Jadenu, Jadenu Sprinkle Prescribing Information. Novartis Pharmaceuticals. East Hanover, NJ. July 2020.
11. AHFS Drug Information (Adult and Pediatric) [Internet database]. Bethesda, Maryland. Lexicomp, Inc. Updated periodically. Available by subscription at: <http://online.lexi.com/>. Accessed on April 8, 2021.
12. Deferasirox tablet Prescribing Information. Cipla USA, Inc. Warren, NJ. August 2020.

4 . Revision History

Date	Notes
4/28/2022	Annual review: No changes to criteria

Demser (metyrosine)

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Prior Authorization Guideline

Guideline ID	GL-133028
Guideline Name	Demser (metyrosine)

Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Demser (metyrosine)
Pheochromocytoma Indicated for the treatment of patients with pheochromocytoma for preoperative preparation of patients for surgery, management of patients when surgery is contraindicated, and chronic treatment of patients with malignant pheochromocytoma. Metyrosine capsules are not recommended for the control of essential hypertension.

2 . Criteria

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Preoperative preparation
Approval Length	1 Time(s)
Guideline Type	Prior Authorization
Approval Criteria	

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:

- plasma free metanephrines
- urinary fractionated metanephrines

AND

2 - Medication is being used for preoperative preparation

AND

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

- alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin)
- beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

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

- Endocrinologist
- Endocrine surgeon

Product Name: Brand Demser, generic metyrosine	
Diagnosis	Treatment of pheochromocytoma
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing:</p> <ul style="list-style-type: none"> • plasma free metanephrines 	

- urinary fractionated metanephrines

AND

2 - Patient with hormonally active (catecholamine excess) pheochromocytoma

AND

3 - One of the following:

3.1 Patient is not a candidate for surgery

OR

3.2 Chronic treatment due to malignant pheochromocytoma

AND

4 - Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol)

AND

5 - Medication will not be used to control essential hypertension

AND

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

- Endocrinologist
- Provider who specializes in the management of pheochromocytoma

Product Name: Brand Demser, generic metyrosine

Diagnosis	Treatment of pheochromocytoma
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks)</p>	

3 . References

1. Metyrosine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. November 2020.
2. Naruse M, Satoh F, Tanabe A, et al. Efficacy and safety of metyrosine in pheochromocytoma/paraganglioma: a multi-center trial in Japan. *Endocrine Journal*. 2018;65(3):359-371.
3. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(6):1915-1942.

4 . Revision History

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

Descovy (emtricitabine/tenofovir alafenamide)



Prior Authorization Guideline

Guideline ID	GL-132900
Guideline Name	Descovy (emtricitabine/tenofovir alafenamide)

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	10/16/2019
P&T Revision Date:	10/21/2020 ; 10/20/2021 ; 03/16/2022 ; 10/19/2022 ; 10/18/2023

1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
<p>Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg.</p> <p>HIV-1 Pre-exposure Prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.</p>

2 . Criteria

Product Name: Descovy	
Diagnosis	Treatment of HIV Infection
Approval Length	24 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Descovy is being used for the treatment of HIV infection</p>	

Product Name: Descovy	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Descovy is being used for HIV Pre-exposure Prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - Patient has a history of intolerance or contraindication to generic Truvada 200/300mg (emtricitabine/tenofovir disoproxil fumarate)</p>	

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. January 2022.

4 . Revision History

Date	Notes
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10/19/2023	Annual review - no changes.
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Dibenzylamine (phenoxybenzamine)

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Prior Authorization Guideline

Guideline ID	GL-121021
Guideline Name	Dibenzylamine (phenoxybenzamine)

Guideline Note:

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

1 . Indications

Drug Name: Dibenzylamine (phenoxybenzamine)
Pheochromocytoma Indicated in the treatment of pheochromocytoma to control episodes of hypertension and swelling.

2 . Criteria

Product Name: Brand Dibenzylamine, generic phenoxybenzamine	
Diagnosis	Pheochromocytoma
Approval Length	1 Time(s) [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: [2]

- plasma free metanephrines
- urinary fractionated metanephrines

AND

2 - Medication is being used for preoperative preparation [A,1]

AND

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

- doxazosin
- terazosin
- prazosin

AND

4 - Treatment will also include a high-sodium diet and fluid intake [B]

AND

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

- Endocrinologist
- Endocrine surgeon

3 . Endnotes

- A. Phenoxybenzamine is most commonly used for preoperative control of blood pressure. Its only current clinical use is in preparing patients with pheochromocytoma for surgery. [1]
- B. Retrospective studies report that initiation of high-sodium diet a few days after the start of alpha-adrenergic receptor blockade reverses blood volume contraction, prevents

orthostatic hypotension before surgery, and reduces the risk of significant hypotension after surgery. [2]

4 . References

1. Farrugia F, Martikos G, Tzanetis P, et al. Pheochromocytoma, diagnosis and treatment: Review of the literature. *Endocrine Regulations*. 2017;51(3):168-181.
2. Lenders JWM, Duh Q-Y, Eisenhofer G, et al. Pheochromocytoma and Paraganglioma: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(6):1915-1942.
3. Phenoxybenzamine Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. December 2020.

5 . Revision History

Date	Notes
3/1/2023	2023 Annual Review - no changes

DPP-4 Inhibitors

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Prior Authorization Guideline

Guideline ID	GL-126402
Guideline Name	DPP-4 Inhibitors

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	2/20/2007
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Not for the treatment of type 1 diabetes, 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUMET.
Drug Name: Januvia (sitagliptin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Januvia should not be used in patients with type 1 diabetes, 2) Januvia has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using JANUVIA.
Drug Name: Tradjenta (linagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Should not be used in patients with type 1 diabetes as it would not be effective, 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using TRADJENTA.

Drug Name: Jentaduetto (linagliptin/metformin), Jentaduetto XR (linagliptin/metformin extended-release)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) should not be used in patients with type 1 diabetes, 2) Has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using JENTADUETO.

2 . Criteria

Product Name: Janumet, Janumet XR, Januvia, Jentaduetto, Jentaduetto XR, Tradjenta	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of a minimum 30 day supply, contraindication, or intolerance to generic metformin</p>	

3 . References

1. Janumet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
2. Janumet XR Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.
3. Januvia Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. July 2022.

4. Jentadueto Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.
5. Jentadueto XR Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. October 2021.
6. Tradjenta Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT. April 2022.

4 . Revision History

Date	Notes
6/7/2023	Annual review: Removed metformin ER, glipizide-metformin, glyburid e-metformin, pioglitazone-metformin as trial options. Updated trial and failure verbiage to include trial duration of 30 days.

Duexis (ibuprofen and famotidine) - PA, NF



Prior Authorization Guideline

Guideline ID	GL-120299
Guideline Name	Duexis (ibuprofen and famotidine) - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	5/17/2018
P&T Revision Date:	02/14/2020 ; 02/14/2020 ; 02/18/2021 ; 09/15/2021 ; 02/17/2022 ; 06/15/2022 ; 2/16/2023

1 . Indications

Drug Name: Duexis (ibuprofen/famotidine)
Osteoarthritis, rheumatoid arthritis, and gastrointestinal ulcers Indicated for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as a gastric and /or duodenal ulcer, in patients who are taking ibuprofen for those indications. The clinical trials primarily enrolled patients less than 65 years of age without a prior history of gastrointestinal ulcer. Controlled trials do not extend beyond 6 months.

2 . Criteria

Product Name: Brand Duexis, generic ibuprofen-famotidine F	
Approval Length	3 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - One of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - History of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - History of a minimum 30 day trial and failure, or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

Product Name: Brand Duexis, generic ibuprofen-famotidine NF

Approval Length	3 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Submission of medical records (e.g., chart notes) documenting one of the following diagnoses:

- Osteoarthritis
- Rheumatoid Arthritis

AND

2 - Submission of medical records (e.g., chart notes) documenting one of the following [2]:

- History of peptic ulcer disease
- History of gastrointestinal (GI) bleeding, obstruction, or perforation
- Erosive esophagitis
- Used in combination with aspirin

AND

3 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generics:

- etodolac
- fenoprofen
- flurbiprofen
- ibuprofen
- indomethacin
- ketoprofen
- ketorolac
- meloxicam
- nabumetone
- naproxen
- oxaprozin
- piroxicam
- sulindac
- tolmetin
- diclofenac

AND

4 - Paid claims or submission of medical records (e.g., chart notes) documenting history of a minimum 30 day trial and failure, contraindication or intolerance to two of the following generic H2-receptor antagonists:

- cimetidine
- famotidine
- nizatidine
- ranitidine

AND

5 - Physician has provided rationale for needing to use fixed-dose combination therapy with brand Duexis or generic ibuprofen-famotidine instead of taking individual products in combination

3 . References

1. Duexis [prescribing information]. Deerfield, IL: Horizon Medicines, LLC; April 2021.
2. Solomon C. Upper Gastrointestinal Bleeding Due to a Peptic Ulcer. N Engl J Med. 2016;374:2367-2376.

4 . Revision History

Date	Notes
1/31/2023	2023 Annual Review

Elmiron (pentosan polysulfate sodium)

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Prior Authorization Guideline

Guideline ID	GL-94072
Guideline Name	Elmiron (pentosan polysulfate sodium)

Guideline Note:

Effective Date:	1/1/2022
P&T Approval Date:	4/21/2021
P&T Revision Date:	

1 . Indications

Drug Name: Elmiron (pentosan polysulfate sodium)
Interstitial Cystitis Indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

2 . Criteria

Product Name: Elmiron	
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

<p>Approval Criteria</p> <p>1 - Diagnosis of interstitial cystitis</p> <p style="text-align: center;">AND</p> <p>2 - Patient has bladder pain or discomfort</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 30 days supply), contraindication, or intolerance to two of the following: [2]</p> <ul style="list-style-type: none"> • Amitriptyline • Cimetidine • Hydroxyzine
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Product Name: Elmiron	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy</p>	

3 . References

1. Elmiron Prescribing Information. Janssen Pharmaceuticals, Inc. Titusville, NJ. June 2020.
2. Hanno PM, Erickson D, Moldwin R, et al. Diagnosis and treatment of interstitial cystitis/bladder pain syndrome: AUA guideline amendment. J Urol . 2015 May;193(5):1545-53. doi: 10.1016/j.juro.2015.01.086.

4 . Revision History

Date	Notes
9/15/2021	Addition of EHB Formulary to guideline

Emsam (selegiline transdermal system)

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Prior Authorization Guideline

Guideline ID	GL-126145
Guideline Name	Emsam (selegiline transdermal system)

Guideline Note:

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

1 . Indications

Drug Name: Emsam (selegiline transdermal system)
Major Depressive Disorder Indicated for the treatment of adults with major depressive disorder (MDD).

2 . Criteria

Product Name: Emsam	
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 - One of the following:

2.1 Trial and failure, contraindication, or intolerance to two of the following generics:

- bupropion
- citalopram
- desvenlafaxine ER
- duloxetine
- escitalopram
- fluoxetine
- mirtazapine
- paroxetine
- paroxetine ER
- sertraline
- venlafaxine
- venlafaxine ER

OR

2.2 For continuation of prior therapy

3 . References

1. Emsam Prescribing Information. Mylan Specialty L.P. Morgantown, WV. May 2020.

4 . Revision History

Date	Notes
7/6/2023	Annual review: No updates required.

Ergot Alkaloids



Prior Authorization Guideline

Guideline ID	GL-122040
Guideline Name	Ergot Alkaloids

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/15/2020
P&T Revision Date:	12/16/2020 ; 04/21/2021 ; 06/16/2021 ; 11/18/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection
Migraine Indicated for the acute treatment of migraine headaches with or without aura. Cluster Headache Indicated for the acute treatment of cluster headache episodes.
Drug Name: Migranal (dihydroergotamine mesylate) nasal spray
Migraine Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.
Drug Name: Cafergot (ergotamine tartrate and caffeine) tablet, Ergomar (ergotamine tartrate) sublingual tablet, Migergot (ergotamine tartrate and caffeine) suppository
Headache Indicated as therapy to abort or prevent vascular headache, e.g., migraine, migraine variants, or so-called “histaminic cephalgia”.
Drug Name: Trudhesa (dihydroergotamine mesylate) nasal spray

Migraine Indicated for the acute treatment of migraine with or without aura in adults.
 Limitations of Use: - Not indicated for the preventive treatment of migraine. - Not indicated for the management of hemiplegic or basilar migraine.

2 . Criteria

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray	
Diagnosis	Migraines
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of migraine headaches with or without aura</p> <p style="text-align: center;">AND</p> <p>2 - Will be used for the acute treatment of migraine</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older [A]</p> <p style="text-align: center;">AND</p> <p>4 - One of the following: [3]</p> <ul style="list-style-type: none"> • Trial and failure or intolerance to two triptans (e.g., eletriptan, rizatriptan, sumatriptan) • Contraindication to all triptans 	

AND

5 - If patient has 4 or more headache days per month, patient must be currently treated with one of the following, unless there is a contraindication or intolerance to these medications: [B, 4]

- An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine])
- An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate])
- A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol)
- Atacand (candesartan)

AND

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

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafegot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, Migergot suppository, Brand Migranal nasal spray, Generic dihydroergotamine mesylate nasal spray, or Trudhesa nasal spray

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

Approval Criteria

1 - Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea)

AND

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

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository

Diagnosis	Cluster Headaches
Approval Length	3 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of cluster headache

AND

2 - Patient is 18 years of age or older [A]

AND

3 - Trial and failure, contraindication, or intolerance to sumatriptan injection [5]

AND

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

- Neurologist
- Pain specialist
- Headache specialist [C]

Product Name: Brand Cafergot tablet, Generic ergotamine tartrate/caffeine tablet, Brand D.H.E. 45 injection, Generic dihydroergotamine mesylate injection, Ergomar sublingual tablet, or Migergot suppository	
Diagnosis	Cluster Headaches
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity</p> <p style="text-align: center;">AND</p> <p>2 - Prescribed by or in consultation with one of the following specialists:</p> <ul style="list-style-type: none"> • Neurologist • Pain specialist • Headache specialist [C] 	

3 . Endnotes

- A. The safety and effectiveness in pediatric patients has not been established. [1, 2]
- B. The American Academy of Neurology supports the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [3, 4]
- C. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS) [6]

4 . References

1. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
2. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.

3. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. *Headache*. 2021 Jul;61(7):1021-1039.
4. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. *Neurology*. 2016 May 10;86(19):1818-26.
5. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016 Jul;56(7):1093-106.
6. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed March 9, 2023.
7. Cafergot Prescribing Information. Sandoz Inc. Princeton, NJ. May 2018
8. Ergomar Prescribing Information. TerSera Therapeutics LLC. Deerfield, IL. February 2020.
9. Migergot Prescribing Information. Cosette Pharmaceuticals, Inc.. South Plainfield, NJ. June 2020.
10. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.

5 . Revision History

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

Extended Release Tramadol Products

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Prior Authorization Guideline

Guideline ID	GL-135214
Guideline Name	Extended Release Tramadol Products

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	11/16/2017
P&T Revision Date:	09/16/2020 ; 01/20/2021 ; 11/18/2021 ; 10/19/2022 ; 10/18/2023

1 . Indications

Drug Name: Conzip
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Drug Name: Tramadol Extended Release (ER)
Pain Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

2 . Criteria

Product Name: ConZip, tramadol ER	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of moderate to moderately severe chronic pain

AND

2 - Trial and failure (of a minimum 30 day supply) or intolerance to an immediate release tramadol containing product [e.g., Ultram (tramadol), Ultracet (tramadol/acetaminophen)]

3 . References

1. Conzip prescribing information. Vectical Pharmaceuticals, LLC. Bridgewater, NJ. September 2021.
2. Tramadol Extended Release prescribing information. Lupin Pharmaceuticals, Inc. Baltimore, MD. September 2021.

4 . Revision History

Date	Notes
10/19/2023	Annual review

Eysuvis (loteprednol etabonate ophthalmic suspension)

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Prior Authorization Guideline

Guideline ID	GL-137429
Guideline Name	Eysuvis (loteprednol etabonate ophthalmic suspension)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/18/2021
P&T Revision Date:	05/20/2021 ; 5/18/2023

1 . Indications

Drug Name: Eysuvis (loteprednol etabonate ophthalmic suspension)
Dry eye disease (DED) Indicated for the short-term (up to two weeks) treatment of the signs and symptoms of dry eye disease.

2 . Criteria

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of dry eye disease

AND

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

- Ophthalmologist
- Optometrist

Product Name: Eysuvis	
Diagnosis	Dry Eye Disease
Approval Length	14 Day(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy (e.g., improvement in dry eye symptoms)

AND

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

- Ophthalmologist
- Optometrist

3 . References

1. Eysuvis prescribing information. Kala Pharmaceuticals, Inc. Watertown, MA. November 2020.

2. Per clinical consult with ophthalmologist, December 21, 2020.
3. Shtein, RM. Dry eye disease. In: Post T, ed. UpToDate. UpToDate; 2020. Accessed December 16, 2020. www.uptodate.com
4. Micromedex Healthcare Series [database on the Internet]. Greenwood Village (CO): IBM Corporation.; Updated periodically. Available by subscription at: <https://www.micromedexsolutions.com/>. Accessed December 16, 2020.

4 . Revision History

Date	Notes
12/6/2023	Updated reauth verbiage to remove documentation requirement

Fecal Microbiota Agents - PA, NF

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Prior Authorization Guideline

Guideline ID	GL-137538
Guideline Name	Fecal Microbiota Agents - PA, NF

Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Rebyota (fecal microbiota, live-jslm) suspension
Recurrent Clostridioides difficile infection (CDI) Indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. Limitations of use: Rebyota is not indicated for treatment of CDI.
Drug Name: Vowst (fecal microbiota spores, live-brpk) capsule
Recurrent Clostridioides difficile infection (CDI) Indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Limitations of use: Vowst is not indicated for treatment of CDI.

2 . Criteria

Product Name: Rebyota	
Approval Length	14 Day(s)

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:</p> <ul style="list-style-type: none">• Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days• A positive stool test for C.difficile toxin or toxigenic C.difficile <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a history of one or more recurrent episodes of CDI</p> <p style="text-align: center;">AND</p> <p>4 - Both of the following:</p> <p>4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:</p> <ul style="list-style-type: none">• oral vancomycin• Difucid (fidaxomicin) <p style="text-align: center;">AND</p> <p>4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)</p> <p style="text-align: center;">AND</p>	

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

- Gastroenterologist
- Infectious disease specialist

Product Name: Rebyota

Approval Length | 14 Day(s)

Guideline Type | Non Formulary

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of one or more recurrent episodes of CDI

AND

4 - Both of the following:

4.1 Paid claims or submission of medical records (e.g., chart notes) confirming patient has completed at least 10 consecutive days of one of the following antibiotic therapies between 24 to 72 hours prior to initiating Rebyota:

- oral vancomycin

<ul style="list-style-type: none"> Dificid (fidaxomicin) <p style="text-align: center;">AND</p> <p>4.2 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> Gastroenterologist Infectious disease specialist
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Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:</p> <ul style="list-style-type: none"> Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days A positive stool test for C.difficile toxin or toxigenic C.difficile <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - Patient has a history of two or more recurrent episodes of CDI within 12 months</p>	

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

AND

6 - Trial and failure, contraindication or intolerance to Rebyota

Product Name: Vowst	
Approval Length	14 Day(s)
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following:

- Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for 2 consecutive days
- A positive stool test for C.difficile toxin or toxigenic C.difficile

AND

2 - Patient is 18 years of age or older

AND

3 - Patient has a history of two or more recurrent episodes of CDI within 12 months

AND

4 - All of the following:

4.1 Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst:

- oral vancomycin
- Dificid (fidaxomicin)

AND

4.2 Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst [A]

AND

4.3 Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days)

AND

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

- Gastroenterologist
- Infectious disease specialist

AND

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

3 . Endnotes

- A. Patients are required to take magnesium citrate 24 hours prior to the first dose of Vowst per the prescribing information. There is currently no efficacy data regarding the use of Vowst without magnesium citrate and the thought is that it helps to clear the antibiotics prior to administration of Vowst. [2,3]

4 . References

1. Rebyota Prescribing Information. Ferring Pharmaceuticals, Inc. Parsippany, NJ. November 2022.
2. Vowst Prescribing Information. Aimmune Therapeutics, Inc. Brisbane, CA. April 2023.
3. Per clinical consult with gastroenterologist, May 3, 2023.

5 . Revision History

Date	Notes
12/8/2023	Addition of EHB formulary. No changes to criteria.

Ferriprox (deferiprone)

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Prior Authorization Guideline

Guideline ID	GL-122328
Guideline Name	Ferriprox (deferiprone)

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/10/2012
P&T Revision Date:	10/16/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 04/21/2021 ; 07/21/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: Ferriprox (deferiprone) Tablets
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 8 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.
Drug Name: Ferriprox (deferiprone) Oral Solution
Iron Overload Indicated for the treatment of transfusional iron overload in adult and pediatric patients 3 years of age and older with thalassemia syndromes, sickle cell disease or other anemias.

2 . Criteria

Product Name: Ferriprox oral solution, Generic deferiprone tablet

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of transfusional iron overload due to one of the following: [1]</p> <ul style="list-style-type: none"> • Thalassemia syndromes • Sickle cell disease • Other transfusion-dependent anemias <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 For Ferriprox oral solution, patient is 3 years of age or older</p> <p style="text-align: center;">OR</p> <p>2.2 For generic deferiprone tablet, patient is 8 years of age or older</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin > 2,500 mcg/L, to one of the following chelation therapy: [A]</p> <ul style="list-style-type: none"> • Generic deferoxamine • Generic deferasirox <p style="text-align: center;">OR</p> <p>3.2 History of contraindication or intolerance to one of the following chelation therapy:</p> <ul style="list-style-type: none"> • Generic deferoxamine 	

- Generic deferasirox

AND

4 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$

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

Approval Criteria

1 - Diagnosis of transfusional iron overload due to one of the following: [1]

- Thalassemia syndromes
- Sickle cell disease
- Other transfusion-dependent anemias

AND

2 - Patient is 8 years of age or older

AND

3 - One of the following:

3.1 Trial (of a minimum 30 day supply) and failure, defined by a serum ferritin $> 2,500$ mcg/L, to one of the following chelation therapy: [A]

- Generic deferoxamine
- Generic deferasirox

OR

3.2 History of contraindication or intolerance to one of the following chelation therapy:

<ul style="list-style-type: none"> • Generic deferoxamine • Generic deferasirox <p style="text-align: center;">AND</p> <p>4 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure, or intolerance to generic deferiprone tablets*</p>	
Notes	*Product may require prior authorization

Product Name: Brand Ferriprox tablet, Ferriprox oral solution, Generic deferiprone tablet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline</p> <p style="text-align: center;">AND</p> <p>2 - Absolute Neutrophil Count (ANC) greater than $1.5 \times 10^9/L$</p>	

3 . Endnotes

A. Failure to prior chelation therapy is defined as serum ferritin > 2,500 mcg/L. [1]

4 . References

1. Ferriprox tablets prescribing information. Apotex Inc., Toronto, Canada. November 2021.
2. Ferriprox solution prescribing information. Apotex Inc., Toronto, Canada. August 2021.
3. Deferiprone prescribing information. Taro Pharmaceutical Industries Ltd. Haifa Bay, Israel. November 2022.

5 . Revision History

Date	Notes
3/8/2023	2023 UM Annual Review. Added age criteria to align with package insert. Removed SP formulary and kept only standard formulary attached to guideline. Updated references

Fibric Acid Derivatives



Prior Authorization Guideline

Guideline ID	GL-132674
Guideline Name	Fibric Acid Derivatives

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 ; 01/18/2023 ; 9/20/2023

1 . Indications

Drug Name: Fenoglide, Fibricor
<p>Primary Hypercholesterolemia and Mixed Dyslipidemia Indicated as adjunctive therapy to diet to reduce elevated low-density lipoprotein cholesterol (LDL-C), total cholesterol (Total-C), triglycerides (TG), and apolipoprotein B (Apo B), and to increase high-density lipoprotein (HDL-C) in adult patients with primary hypercholesterolemia or mixed dyslipidemia. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.</p> <p>Severe Hypertriglyceridemia Indicated as adjunctive therapy to diet for treatment of adult patients with severe hypertriglyceridemia. Improving glycemic control in diabetic patients showing fasting chylomicronemia will usually reduce fasting triglycerides and eliminate chylomicronemia thereby obviating the need for pharmacologic intervention. Markedly elevated levels of serum triglycerides (e.g., > 2000 mg/dL) may increase the risk of developing pancreatitis. The effect of fenofibrate therapy on reducing this risk has not been adequately studied. Limitations of Use: Fenofibrate was not shown to reduce coronary heart disease morbidity and mortality in patients with type 2 diabetes mellitus.</p>

2 . Criteria

Product Name: Brand Fenoglide, Brand Fibracor	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure or intolerance to a minimum 30 day supply to both of the following:</p> <p>2.1 One of the following generics:</p> <ul style="list-style-type: none">• fenofibrate micronized capsule• fenofibrate tablet• fenofibric capsule• fenofibric acid tablet <p style="text-align: center;">AND</p> <p>2.2 One of the following:</p> <ul style="list-style-type: none">• Brand Lipofen• Generic fenofibrate capsule	

3 . References

1. Fenoglide Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. June 2021.
2. Fibracor Prescribing Information. Athena Bioscience, LLC. Athena, GA. December 2020.

4 . Revision History

Date	Notes
9/6/2023	Annual Review - No criteria changes

Flurazepam

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Prior Authorization Guideline

Guideline ID	GL-120544
Guideline Name	Flurazepam

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	7/10/2012
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Flurazepam
Insomnia Indicated for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Since insomnia is often transient and intermittent, short-term use is usually sufficient. Prolonged use of hypnotics is usually not indicated and should only be undertaken concomitantly with appropriate evaluation of the patient.

2 . Criteria

Product Name: Flurazepam	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of insomnia

AND

2 - Trial and failure, contraindication, or intolerance to two of the following benzodiazepines:
[A]

- Estazolam
- Halcion (triazolam)
- Restoril (temazepam)

3 . Endnotes

- A. Flurazepam, estazolam, triazolam, and temazepam are only recommended for patients < 65 years old. These drugs are included on the American Geriatrics Society 2019 Beers Criteria update. [2]

4 . References

1. Flurazepam Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. February 2021.
2. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

5 . Revision History

Date	Notes
3/16/2023	Annual review: no changes to criteria.

Generic-First Step Program



Prior Authorization Guideline

Guideline ID	GL-135379
Guideline Name	Generic-First Step Program

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/14/2019
P&T Revision Date:	11/14/2019 ; 12/18/2019 ; 01/15/2020 ; 01/15/2020 ; 02/13/2020 ; 08/13/2020 ; 11/12/2020 ; 07/21/2021 ; 10/20/2021 ; 11/18/2021 ; 12/15/2021 ; 03/16/2022 ; 04/20/2022 ; 08/18/2022 ; 08/18/2022 ; 10/19/2022 ; 04/20/2022 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 04/19/2023 ; 09/20/2023 ; 10/18/2023 ; 5/18/2023

1 . Criteria

Product Name: Brand contraceptive drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Both of the following:</p>	

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- The requested product is medically necessary**

OR

1.2 Both of the following:

- Patient is using the prescribed drug for contraception or other FDA-approved condition*
- Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart

Notes	*Examples of non-contraception uses: (1) Abnormal or excessive bleeding disorders (eg, amenorrhea, oligomenorrhea, menorrhagia, dysfunctional uterine bleeding); (2) Acne; (3) Decrease in bone mineral density; (4) Dysmenorrhea; (5) Endometriosis; (6) Hirsutism; (7) Irregular menses / cycles; (8) Ovarian cysts; (9) Perimenopausal symptoms; (10) History of Pelvic Inflammatory Disease (PID); (11) Polycystic Ovarian Syndrome (PCO or PCOS); (12) Premenstrual Syndrome (PMS); (13) Premenstrual Dysphoric Disorder (PMDD); (14) Prevention of endometrial and/or ovarian cancer; (15) Prevention of menstrual migraines; (16) Turner's syndrome; (17) Uterine fibroids or adenomyosis. **Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access.
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Product Name: Brand drug which has a generic counterpart	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of a minimum 30 day supply, or intolerance to target's generic counterpart</p>	

2 . Background

Benefit/Coverage/Program Information	
Table of Target Drugs which require trial and failure or intolerance to generic counterpart	
ABILIFY	592500150003**
ALTACE	361000500001**
ARIMIDEX	21402810000310
ARTHROTEC 75 TAB	66109902200630
ATACAND	361500201003**
AVAPRO	361500300003**
AVODART CAP 0.5MG	56851020000120
AZOPT	86802320001820
BRISDELLE CAP 7.5MG	62226060300110
BYSTOLIC	332000401003**
CANASA SUP 1000MG	52500030005240
CARBATROL	726000200069**
CARDIZEM LA	340000101275**
CARNITOR SOL 1GM/10ML	30903045102010

CARNITOR TAB 330MG	30903045100330
CATAPRES-TTS	362010100088**
CELEXA	581600201003**
CIALIS	403040800003**
CIALIS TAB 2.5MG	40304080000302
CIALIS TAB 5MG	40304080000305
CLARINEX TAB 5MG	41550021000320
CLIMARA	240000350088**
CLOBEX LOT 0.05%	90550025104110
CLOBEX SHA 0.05%	90550025104520
CLOBEX SPR 0.05%	90550025100910
COLESTID	391000201027**
COLESTID	391000201030**
COLESTID TAB 1GM	39100020100320
COREG	333000070003**
COREG CR	333000072070**
CORTEF	221000250003**
COSOPT SOL 22.3- 6.8	86259902202020

COSOPT PF SOL	86259902202060
COZAAR	361500402003**
DELESTROGEN INJ	240000352017**
DEPAKOTE ER	725000101075**
DEPAKOTE	725000101006**
DEPAKOTE SPR CAP 125MG	7250001010H120
EFFEXOR XR	581800901070**
EPIDUO GEL 0.1- 2.5%	90059902034020
ESTRACE	240000350003**
ESTRACE VAG CRE 0.01%	55350020003705
EXFORGE	369930021003**
FIORICET CAP	64991003100108
FIORICET CAP CODEINE	65991004100113
FLOMAX CAP 0.4MG	56852070100110
GENERESS FE CHW	25990003600540
GOLYTELY	469920053021**
HYZAAR	369940024503**
IMITREX INJ	6740607010D5**
IMITREX INJ	6740607010E2**

IMITREX INJ 6MG/0.5	674060701020**
IMITREX SPRAY	674060700020**
IMITREX TABLET	674060701003**
KEPPRA	726000430003**
KEPPRA SOL 100MG/ML	72600043002020
KEPPRA XR	726000430075**
KLONOPIN	721000100003**
KLONOPIN TAB 2MG	72100010000315
K-TAB	797000300004**
LATUDA	5940002310**
LAMICTAL	726000400003**
LAMICTAL	726000400005**
LAMICTAL KIT START 35	72600040006420
LAMICTAL KIT START 49	72600040006430
LAMICTAL KIT START 98	72600040006435
LAMICTAL ODT	726000400072**
LAMICTAL ODT KIT	72600040006450
LAMICTAL ODT KIT	72600040006455

LAMICTAL ODT KIT	72600040006460
LAMICTAL XR	726000400075**
LASIX	372000300003**
LOESTRIN TAB 1/20-21	25990002600310
LOESTRIN 21 TAB 1.5/30	25990002600320
LOESTRIN FE TAB 1.5/30	25990003610320
LOESTRIN FE TAB 1/20	25990003610310
LOTREL	369915022001**
LYRICA	726000570001**
LYRICA CAP 300MG	72600057000160
LYRICA SOL 20MG/ML	72600057002020
MAXALT	674060601003**
MAXALT-MLT	674060601072**
MICARDIS	361500700003**
MICARDIS HCT	369940026003**
MOBIC	661000520003**
NALFON CAP 400MG	66100010100120
NALFON TAB 600MG	66100010100305

NATROBA SUS 0.9%	90900048001820
NEURONTIN	726000300001**
NEURONTIN	726000300003**
NEURONTIN SOL 250/5ML	72600030002020
NIASPAN	394500500004**
PAXIL	581600600003**
PAXIL CR	581600600075**
PLAQUENIL TAB 200MG	13000020100305
PLAVIX	851580201003**
PRED FORTE SUS 1% OP	86300050101815
PRINIVIL	361000300003**
QUESTRAN	391000100029**
RANEXA	322000400074**
RELPAX	674060251003**
RENAGEL	528000701003**
RESTORIL	602010300001**
RISPERDAL	590700700003**
RISPERDAL SOL 1MG/ML	59070070002010
SAFYRAL TAB	25990003200330

SEASONIQUE TAB	25993002300330
SEROQUEL	591530701003**
SEROQUEL TAB 300MG	59153070100340
SEROQUEL TAB 400MG	59153070100350
SEROQUEL XR	591530701075**
SEROQUEL XR TAB 200MG	59153070107520
SILVADENE CRE 1%	90450030003710
SKELAXIN TAB 800MG	75100060000320
SOMA	751000200003**
SUBOXONE MIS 12-3MG	65200010208250
SUBOXONE MIS 2- 0.5MG	65200010208220
SUBOXONE MIS 4- 1MG	65200010208230
SUBOXONE MIS 8- 2MG	65200010208240
TAMIFLU SUS 6MG/ML	12504060201910
TEGRETOL SUS 100/5ML	72600020001810
TEGRETOL TAB 200MG	72600020000305

TEGRETOL-XR	726000200074**
TENORMIN	332000200003**
TIKOSYN	354000250001**
TIMOPTIC SOL 0.25% OP	86250030102005
TIMOPTIC SOL 0.5% OP	86250030102010
TIMOPTIC OCU SOL 0.25% OP	86250030102006
TIMOPTIC OCU SOL 0.5% OP	86250030102011
TIMOPTIC-XE SOL 0.5% OP	86250030107630
TIMOPTIC-XE SOL 0.25% OP	86250030107620
TOPAMAX	726000750003**
TOPAMAX SPR	726000750068**
TRAVATAN Z	86330070002025
TRICOR TAB 145MG	39200025000323
TRICOR TAB 48MG	39200025000310
TRILEPTAL	726000460003**
TRILEPTAL SUS 300MG/5M	72600046001820
UCERIS TAB 9MG	22100012007530

VALTREX		124050851003**
VANADOM		75100020000305
VECTICAL 3MCG/GM	OIN	90250028004220
VESICARE		541000552003**
VIGAMOX 0.5%	DRO	86101038102020
WELCHOL 3.75GM	PAK	39100016103040
WELCHOL 625MG	TAB	39100016100330
XALATAN 0.005%	SOL	86330050002020
YASMIN 28 0.03MG	TAB 3-	25990002150320
ZANAFLEX		751000901001**
ZANAFLEX 4MG	TAB	75100090100320
ZESTRIL		361000300003**
ZONEGRAN		726000900001**
ZOVIRAX CRE 5%		90350010003720
ZYPREXA		591570600003**
ZYPREXA 10MG	INJ	59157060002120
BROVANA		442010121025**
NITRO-DUR		321000300085**

LATISSE	90734020002020
NITROSTAT	32100030000710
NITROSTAT	32100030000715
NITROSTAT	32100030000720
TOPICORT	90550040000910
ARTHROTEC 50	66109902200620
PROPECIA	90736030000310
ZOVIRAX	90350010004205
HALOG	90550070003710
DILANTIN-125	72200030001810
COMBIGAN	862599021520**
ZOLOFT	581600701003**
ACZONE	90051015004020
ACZONE	90051015004030
VIMPAT	726000360003**
VIMPAT	72600036002020
VIMPAT	72600036002060
KENALOG-40	22100050101810

3 . Revision History

Formulary: Baylor Scott and White – EHB, Non-Specialty

Date	Notes
10/24/2023	update guideline

GLP-1 Agonists



Prior Authorization Guideline

Guideline ID	GL-136590
Guideline Name	GLP-1 Agonists

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	6/7/2005
P&T Revision Date:	12/18/2019 ; 02/13/2020 ; 03/18/2020 ; 05/14/2020 ; 10/21/2020 ; 04/21/2021 ; 06/16/2021 ; 05/19/2022 ; 06/15/2022 ; 07/20/2022 ; 08/18/2022 ; 01/18/2023 ; 02/16/2023 ; 05/18/2023 ; 06/21/2023 ; 08/17/2023 ; 04/19/2023 ; 12/13/2023

1 . Indications

Drug Name: Adlyxin (lixisenatide)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis, 2) Adlyxin should not be used in patients with type 1 diabetes mellitus, 3) Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.
Drug Name: Byetta (exenatide injection)
Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: 1) Byetta is not indicated for use in patients with type 1 diabetes, 2) Byetta contains exenatide and should not be used with other products containing the active ingredient exenatide. 3) Byetta has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Drug Name: Bydureon BCise (exenatide extended-release)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: 1) Bydureon BCise is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rat thyroid C-cell tumor findings to humans, 2) Bydureon BCise is not indicated for use in patients with type 1 diabetes mellitus, 3) Bydureon BCise is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide, 4) Bydureon BCise has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Drug Name: Ozempic (semaglutide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of use: 1) Ozempic has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy in patients with a history of pancreatitis, 2) Ozempic is not indicated for use in patients with type 1 diabetes mellitus.

Drug Name: Trulicity (dulaglutide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors. Limitations of Use: 1) Trulicity has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis, 2) should not be used in patients with type 1 diabetes mellitus, 3) has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and is therefore not recommended in these patients.

Drug Name: Victoza (liraglutide injection)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus, and is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: 1) Victoza should not be used in patients with type 1 diabetes mellitus, 2) contains liraglutide and should not be coadministered with other liraglutide-containing products.

Drug Name: Mounjaro (tirzepatide)

Type 2 Diabetes Mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Mounjaro has not been

studied in patients with a history of pancreatitis. It is not indicated for use in patients with type 1 diabetes mellitus.

Drug Name: Rybelsus (semaglutide)

Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: (1) RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. (2) RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus.

2 . Criteria

Product Name: Byetta^{*,**}, Bydureon BCise^{*,**}, Mounjaro^{*,**}, Ozempic^{*,**}, Rybelsus^{*,**}, Trulicity^{*,**}, Victoza^{*,**}

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

Approval Criteria

1 - One of the following:

1.1 For patients requiring ongoing drug treatment for type 2 diabetes mellitus, submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus

OR

1.2 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values:

- A1C greater than or equal to 6.5%
- Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
- 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL) during OGTT (oral glucose tolerance test)

Notes	*If being used for any other indications, deny the case for medical necessity and do not review for off-label use. **If patient meets criteria above, please approve at GPI-10.
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Product Name: Byetta*, Bydureon BCise*, Mounjaro*, Ozempic*, Rybelsus*, Trulicity*, Victoza*	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	
Notes	* If patient meets criteria above, please approve at GPI-10.

Product Name: Adlyxin*	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 For patients requiring ongoing drug treatment for type 2 diabetes mellitus, submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">OR</p> <p>1.2 Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by one of the following laboratory values:</p> <ul style="list-style-type: none"> • A1C greater than or equal to 6.5% • Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL 	

<ul style="list-style-type: none"> • 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL) during OGTT (oral glucose tolerance test) <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 90-day supply) at the maximally tolerated dose, contraindication, or intolerance to one metformin-containing agent</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure (of a minimum 90-day supply) or intolerance to two of the following preferred brands:</p> <ul style="list-style-type: none"> • Bydureon/Bydureon BCise • Byetta • Ozempic • Trulicity • Victoza • Rybelsus • Mounjaro 	
Notes	*If being used for any other indications, deny the case for medical necessity and do not review for off-label use

Product Name: Adlyxin	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

3 . Endnotes

- A. In people with CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA with proven benefit should be independent of background use of

metformin. The GLP-1 RAs that have shown proven benefit include Ozempic, Trulicity, and Victoza [9].

4 . References

1. Byetta Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. June 2022.
2. Victoza Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. June 2022.
3. Trulicity Prescribing Information. Eli Lilly and Company. Indianapolis, IN. December 2022.
4. Adlyxin Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. July 2021.
5. Bydureon BCise Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. May 2023.
6. Ozempic Prescribing Information. Novo Nordisk Inc. Plainsboro, NJ. October 2022.
7. Mounjaro Prescribing Information. Eli Lilly and Company. Indianapolis, IN. May 2023.
8. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. December 2022.
9. American Diabetes Association (ADA) 2023 Standards of Care in Diabetes to Guide Prevention, Diagnosis, and Treatment for People Living with Diabetes. Accessed May 18, 2023.

5 . Revision History

Date	Notes
11/30/2023	Removed t/f of metformin

Glumetza (metformin ER tablets)



Prior Authorization Guideline

Guideline ID	GL-125129
Guideline Name	Glumetza (metformin ER tablets)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	5/17/2011
P&T Revision Date:	05/14/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Glumetza (metformin ER tablets)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

2 . Criteria

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR) [A]

AND

1.1.2 Documented history of an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by Hemoglobin A1c level above patient's goal

OR

1.2 Documented history of intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

AND

2 - One of the following:

2.1 Both of the following:

2.1.1 History of greater than or equal to 12 week trial of metformin immediate-release

AND

2.1.2 Documented history of an inadequate response to metformin immediate-release as evidenced by Hemoglobin A1c level above patient's goal

OR

2.2 Documented history of intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction)

Product Name: Brand Glumetza, Generic metformin ER 24 HR tablet [Generic Glumetza]	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has experienced an objective response to therapy demonstrated by an improvement in HbA1c from baseline</p>	

3 . Endnotes

- A. Prior authorization promotes use of cost-effective metformin options prior to approval of Glumetza (metformin extended release). Glucophage XR (metformin extended release) is also a 24 hour tablet preparation and is available generically.

4 . References

1. Glumetza Prescribing Information. Salix Pharmaceuticals. Bridgewater, NJ. August 2019.

5 . Revision History

Date	Notes
6/22/2023	Annual review - no changes.

Halcinonide cream

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Prior Authorization Guideline

Guideline ID	GL-126146
Guideline Name	Halcinonide cream

Guideline Note:

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

1 . Indications

Drug Name: Halcinonide cream
Corticosteroid-responsive dermatoses Indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

2 . Criteria

Product Name: Halcinonide cream	
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, contraindication, or intolerance to three of the following generics:

- betamethasone dipropionate 0.05% ointment
- betamethasone augmented 0.05% cream
- desoximetasone 0.25% cream
- fluocinonide 0.05% solution
- fluocinonide 0.05% cream
- fluocinonide 0.05% gel
- fluocinonide 0.05% ointment

3 . References

1. Halcinonide Prescribing Information. Glasshouse Pharmaceuticals Limited Canada. Ontario, Canada. October 2020.

4 . Revision History

Date	Notes
7/6/2023	Annual review: No updates required.

Healthcare Reform Copay Waiver Review

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Prior Authorization Guideline

Guideline ID	GL-133757
Guideline Name	Healthcare Reform Copay Waiver Review

Guideline Note:

Effective Date:	1/1/2024
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Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name: Fluoride supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	
1 - Patient is between 6 months of age to 16 years of age*	

AND	
<p>2 - Requested product is a prescription (single ingredient only) oral fluoride supplementation product (does not include topical fluoride products such as toothpaste or rinses, etc.)</p>	
AND	
<p>3 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)</p>	
Notes	<p>*Benefit exclusion if age not met. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.</p>

Product Name: Folic acid supplementation products	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Patient is of childbearing potential who is planning pregnancy*</p> <p style="text-align: center;">AND</p> <p>2 - Requested product is a prescription or OTC folic acid product (with prescription), including prenatal vitamins containing folic acid*</p> <p style="text-align: center;">AND</p> <p>3 - Requested product contains between 0.4 mg to 0.8 mg of folic acid**</p> <p style="text-align: center;">AND</p>	

<p>4 - There is a clinical reason why the patient cannot take two products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response)</p>	
Notes	<p>*Benefit exclusion if not for childbearing or for multivitamins without folic acid. **Greater than 0.8mg is allowed for medical necessity. ***The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.</p>

<p>Product Name: Smoking Cessation products</p>	
Approval Length	6 months per 12 months for zero copay with deductible bypass
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older*</p> <p style="text-align: center;">AND</p> <p>2 - For use as an aid to smoking cessation treatment*</p> <p style="text-align: center;">AND</p> <p>3 - Any requested HCR \$0 Rx or OTC smoking cessation product and quantity requested does not exceed the following quantities:</p> <ul style="list-style-type: none"> • Maximum of 180 days of therapy per year for all smoking cessation products • Varenicline/Apo-Varenicline: starter kits limited to one 53 tablet starter kit; Maximum Daily Dose (MDD) = 2 units per day for remainder of therapy • Nicotrol NS: MDD = 4 mL per day • Nicotrol Inhaler: MDD = 16 units per day • Zyban/Buproban/bupropion 150 mg SR: MDD = 2 • Brand or Generic OTC Nicotine replacement patch: MDD = 1 • Brand or Generic OTC Nicotine replacement gum: MDD = 24 • Brand or Generic OTC Nicotine replacement lozenge: MDD = 20 <p style="text-align: center;">AND</p>	

4 - If request is for Nicotrol inhaler, Nicotrol NS, or Apo-Varenicline, a history of both of the following:

4.1 Generic Zyban (bupropion)

AND

4.2 One of the following smoking cessation therapies:

- Nicotine gum
- Nicotine lozenge
- Nicotine transdermal patch
- Generic varenicline

Notes	*Benefit exclusion if age not met or not used for smoking cessation or used beyond 180 days.
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Product Name: Aspirin	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Patient meets the following*:</p> <p>1.1 Patient is using 81 mg aspirin for the prevention of morbidity and mortality from preeclampsia</p> <p style="text-align: center;">AND</p> <p>1.2 Requested product is a single agent oral OTC aspirin product (with prescription) (but does not include prescription aspirin products, non-oral aspirin products, or aspirin strengths greater than 81 mg)</p>	
Notes	*Benefit exclusion if any criterion is not met.

Product Name: Immunizations	
Approval Length	12 month(s)

Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Requested product is a single-entity or combination vaccination for one of the following:**</p> <ul style="list-style-type: none">• Diphtheria• Haemophilus influenzae type B (applies only to children less than 6 years of age)*• Hepatitis A• Hepatitis B (Hepelisav B applies only to adults ages 18 years and older)*• Herpes zoster (Shingrix applies to adults ages 19 years and older)*• Human papillomavirus (applies only to children and adults 9 years to 26 years of age)*• Polio• Influenza (Flumist applies only to children and adults 2 years through 49 years of age. Fluzone HD Quad, Fluad Quad applies only to adults ages 65 years and older)*• Measles• Mumps• Rubella• Meningococcal infections• Pertussis• Pneumococcal infections• Rotavirus (applies only to children less than 8 months)*• Tetanus• Varicella <p style="text-align: center;">OR</p> <p>2 - All of the following:</p> <p>2.1 Requested product is for Dengvaxia vaccine:</p> <p style="text-align: center;">AND</p> <p>2.2 Member is between ages 9-16 living in a dengue endemic area (endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau)***</p> <p style="text-align: center;">AND</p> <p>2.3 Member has a laboratory confirmation of a previous dengue infection</p>	

Notes	<p>*Benefit exclusion if age not met. **This list excludes vaccines not listed in the Advisory Committee on Immunization Practices (ACIP) Immunization Schedules (http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html).</p> <p>***For updated guidance on dengue endemic areas and pre-vaccination on laboratory testing see: https://www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm and https://www.cdc.gov/dengue/vaccine/hcp/index.html</p>
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Product Name: Bowel preparation agents for colorectal cancer screening [E]	
Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Requested product is a prescription bowel preparation agent used for primary preventative colorectal cancer screening (e.g., patient does not have a previous history of adenomatous polyps or previous colorectal cancer)*</p> <p style="text-align: center;">AND</p> <p>2 - There is a clinical reason why the patient cannot take two generic products on the HCR preventive drug list** (e.g., the patient has had an allergic reaction or intolerance to an inactive ingredient or has experienced an inadequate response). (Some examples of generic bowel prep products include: TriLyte, Gavilyte, PEG-3350/electrolytes)</p> <p style="text-align: center;">AND</p> <p>3 - Quantity requested does not exceed the QL of two primary preventative bowel prep products per year***</p>	
Notes	<p>*Benefit exclusion if not for cancer screening. **The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document. ***If a patient has an intolerance, allergic reaction, or an inadequate response to one of the products on the HCR preventative drug list, then the quantity limits will not apply for one time only per drug category (to allow for another product to be tried on the HCR preventative drug list).</p>

Product Name: Arimidex (anastrozole) 1 mg, Aromasin (exemestane) 25 mg, Evista (raloxifene) 60 mg, Soltamox (tamoxifen) solution, Tamoxifen 20 mg tablets	
Approval Length	60 Months: Authorization will be issued for zero copay with deductible bypass for a total of up to 60 months (please determine if member has already received some length of therapy and if so subtract from total approval period).
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Member is greater than or equal to 35 years of age*</p> <p style="text-align: center;">AND</p> <p>2 - Member has no prior diagnosis of any of the following:*</p> <ul style="list-style-type: none"> • breast cancer • ductal carcinoma in situ (DCIS) <p style="text-align: center;">AND</p> <p>3 - Member has no history of thromboembolic events (e.g.- deep venous thrombosis, pulmonary embolus, stroke or transient ischemic attack)*</p> <p style="text-align: center;">AND</p> <p>4 - Member has an estimated 5 year risk of breast cancer based on a breast cancer risk assessment tool of greater than or equal to 3% [11]*</p> <p style="text-align: center;">AND</p> <p>5 - One of the following:</p> <p style="padding-left: 20px;">5.1 Request is for tamoxifen 20 mg once daily</p>	

OR

5.2 Both of the following:

5.2.1 Member is post-menopausal

AND

5.2.2 One of the following:

5.2.2.1 Request is for raloxifene 60 mg once daily, exemestane 25 mg once daily, or anastrozole 1 mg once daily

OR

5.2.2.2 Request is for brand name Evista 60 mg, Aromasin 25 mg, and Arimidex 1 mg once daily and member has had failure, contraindication or adverse reaction to generic raloxifene, exemestane, or anastrozole

OR

5.3 Both of the following:

5.3.1 Request is for Soltamox 20 mg once daily*

AND

5.3.2 Member has had failure, contraindication or adverse reaction to tamoxifen tablets

Notes

*Benefit exclusion if age not met or has prior cancer diagnosis or has thromboembolic events or less than 3% risk factor or requesting a different strength. This program is designed to meet Health Care Reform requirements which require coverage of tamoxifen tablets, Soltamox (tamoxifen) solution, Evista (raloxifene), Aromasin (exemestane), and Arimidex (anastrozole) at zero dollar cost share if being used for primary prevention of breast cancer and criteria are met.

Product Name: Generic Statins	
Approval Length	24 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Request is for atorvastatin 10 mg or 20 mg, simvastatin 5 mg, 10 mg, 20 mg, or 40mg*</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 Request is for another moderate or low dose statin (pravastatin 10 mg, 20 mg, 40 mg, or 80 mg; fluvastatin 20 mg or 40 mg; pitavastatin 1 mg, 2 mg, or 4 mg; rosuvastatin 5 mg or 10 mg) (D)*</p> <p style="text-align: center;">AND</p> <p>1.2.2 Patient is unable to take all of the following:</p> <ul style="list-style-type: none">• atorvastatin 10 mg or 20 mg• simvastatin 5 mg, 10 mg, 20 mg, or 40 mg• lovastatin (any strength) <p style="text-align: center;">AND</p> <p>2 - Patient is at least 40 years old and younger than 75 years old*</p> <p style="text-align: center;">AND</p> <p>3 - Medication is being used for primary prevention of cardiovascular disease (CVD) (e.g., member has no history of cardiovascular events)*</p>	

AND	
4 - Patient has one or more risk factors for CVD (e.g., dyslipidemia, diabetes, hypertension, or smoking)*	
AND	
5 - Patient has an estimated 10-year risk of a cardiovascular event of 10% or greater*	
Notes	*Benefit exclusion if any criterion not met. The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document .

Product Name: Erythromycin 0.5% ophthalmic ointment	
Approval Length	1 Month: Authorization will be issued for zero copay with deductible bypass for up to 1 month
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Member or health care provider intends to administer medication to newborn for the prophylaxis of gonococcal ophthalmia*</p> <p style="text-align: center;">OR</p> <p>2 - Newborn is 0-1 month of age**</p>	
Notes	*Please note, requests may be submitted before the infant’s birth, and could be requested under the mother’s account. **Benefit exclusion if age exceeded. This program is designed to meet Health Care Reform requirements which require coverage of erythromycin 0.5% ophthalmic ointment at zero dollar cost share if being used for primary prevention of gonococcal ophthalmia neonatorum (GON) and criteria are met. [H] The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document .

Product Name: Brand Truvada 200-300 mg, Generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, Brand Viread 300mg, generic tenofovir disoproxil fumarate 300mg, Descovy	
Approval Length	12 Months: Authorization will be issued for zero copay with deductible bypass for 12 months
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Member is taking as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Request is for generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg or generic tenofovir disoproxil fumarate 300mg</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg (Applies to Brand Truvada 200-300 mg and Descovy only)</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.3 History of contraindication or intolerance to generic tenofovir disoproxil fumarate 300mg (Applies to Brand Viread 300mg only)</p>	
Notes	This program is designed to meet Health Care Reform requirements which require coverage of effective HIV Prep regimens at zero dollar cost share if being used for pre-exposure prophylaxis (PrEP) and criteria are met. [I] *The HCR preventive drug list is posted at: https://uhgaz.ure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document .

Product Name: Aprelude	
Approval Length	12 Months: Authorization will be issued for zero copay with deductible bypass for 12 months

Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Member is taking as effective antiretroviral therapy for pre-exposure prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 History of contraindication or intolerance to generic emtricitabine-tenofovir disoproxil fumarate 200-300 mg, generic tenofovir disoproxil fumarate 300mg, or Descovy</p> <p style="text-align: center;">OR</p> <p> 2.2 Provider attests to both of the following:</p> <ul style="list-style-type: none"> • Patient would benefit from long-acting injectable therapy over standard oral regimens • Patient would be adherent to testing and dosing schedule 	
Notes	<p>This program is designed to meet Health Care Reform requirements which require coverage of effective HIV Prep regimens at zero dollar cost share if being used for pre-exposure prophylaxis (PrEP) and criteria are met. [I] *The HCR preventive drug list is posted at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document.</p>

2 . Endnotes

- A. Important Risk Factors for Breast Cancer [5]: (1) Family history of breast or ovarian cancer (especially among first-degree relatives and onset before age 50 years); (2) History of atypical hyperplasia; (3) Non-malignant high-risk breast lesions; (4) Previous breast biopsy; (5) Extremely dense breast tissue; (6) Increasing age; (7) Race or ethnicity; (8) Age at menarche; (9) Age at first live childbirth; (10) Ductal carcinoma in situ (DCIS); (11) Lobular carcinoma in situ (LCIS); (12) Body mass index; (13) Menopause status or age; (14) Estrogen and progestin use; (15) Smoking; (16) Alcohol use; (17) Physical activity; (18) Diet.
- B. The Affordable Care Act (ACA) requires private insurers to cover certain preventive services without any patient cost-sharing (i.e., copayments) when they are delivered by a network provider. The Department of Health and Human Services (HHS) has

recognized several recommending bodies (e.g., United States Preventive Services Task Force [USPSTF], Advisory Committee on Immunization Practices [ACIP] <http://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/index.html>, Health Resources and Services Administration [HRSA]) who have identified several medication categories that fall within the preventive health mandate.

- C. OptumRx has developed a Healthcare Reform Preventative Drug List posted at: <https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document> that identifies which products are eligible for coverage without patient copayment. Some products may be excluded (such as brand oral contraceptives) unless the patient meets the criteria in this exceptions policy.
- D. Here is a brief summary of the exceptions allowed in this policy (provided the patient meets all of the specified criteria): (1) The fluoride supplementation exception allows for brand name products at no cost-share, but not combination products; (2) The folic acid exception allows for brand name and Rx products at no cost-share; (3) The smoking cessation exception allows for Nicotrol Inhaler, Nicotrol NS, and brand Zyban at no cost-share, but not additional quantities beyond the QLs; all other covered tobacco cessation products for members ages 18 years and older and not to exceed listed QLs; (4) The contraceptives exception allows for brand name products at no cost-share; (5) The bowel preparation agent exception allows for brand name Rx products at no cost-share but not beyond the QL; and (6) The statin exception allows for atorvastatin 10 mg or 20 mg, or simvastatin 5 mg, 10 mg, 20 mg, or 40mg generics at no cost-share. Other moderate to low dose statins include: pravastatin 10 mg, 20 mg, 40 mg, or 80 mg, fluvastatin 20 mg or 40 mg, pitavastatin 1 mg or 2 mg or 4 mg, rosuvastatin 5 mg or 10 mg.
- E. Bowel Preparation Agents: It is important to distinguish between a screening and a surveillance or diagnostic colonoscopy. Screening is performed in asymptomatic patients with no history of colon cancer, polyps, and/or gastrointestinal disease. [1] Whereas, a surveillance colonoscopy can be performed at varying ages and intervals based on the patient's personal history of colon cancer, polyps, and/or gastrointestinal disease. Patients with a history of colon polyp(s) are not recommended for a screening colonoscopy, but for a surveillance colonoscopy. Per the USPSTF, when the screening test results in the diagnosis of clinically significant colorectal adenomas or cancer, the patient will be followed by a surveillance regimen, and recommendations for screening are no longer applicable. [6] According to the USPSTF, routine colorectal cancer screening is now recommended in adults beginning at age 45 and continuing only until age 75. The American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology jointly recommended screening for colorectal cancer beginning at 45 years of age by 1) high-sensitivity FOBT or fecal immunochemical testing annually, 2) flexible sigmoidoscopy every 5 years, 3) CT colonography (virtual colonoscopy) every 5 years, 4) colonoscopy every 10 years, or 5) fecal DNA at an unspecified interval. Based on the collective information above, we have a quantity limit in place of two bowel preparation agents per year. (This quantity limit will not apply if patient was intolerant to, had an allergic reaction, or an inadequate response to one of the bowel prep products on the HCR preventative drug list.)
- F. Breast Cancer Prevention: The USPSTF recommends that clinicians engage in shared, informed decision-making with women who are at increased risk for breast cancer about medications to reduce their risk. [5] For women who are at an increased risk for breast cancer and at low risk for adverse medication effects, clinicians should offer to prescribe risk-reducing medications, such as tamoxifen or raloxifene. The USPSTF recommends against the routine use of medications, such as tamoxifen or raloxifene, for risk reduction

of primary breast cancer in women who are not at increased risk for breast cancer. The updated STAR trial results show diminished benefits of raloxifene compared to tamoxifen after cessation of therapy, making it a preferred risk reduction choice for most post-menopausal women desiring non-surgical risk reduction therapy. However, consideration of toxicity (e.g., endometrial cancer or uterine bleeding) may still lead to the choice of raloxifene over tamoxifen in some women.

- G. Gonococcal Ophthalmia Neonatorum (GON) Prevention: The USPSTF recommends prophylactic ocular topical medication for all newborns to prevent gonococcal ophthalmia neonatorum (GON). [17] GON can cause corneal scarring, ocular perforation, and blindness as early as 24 hours after birth. Erythromycin ophthalmic ointment is the only FDA approved drug for the prophylaxis of GON. Ocular prophylaxis of newborns is mandated in most states and is considered standard neonatal care.
- H. The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. [19] Once-daily oral treatment with Truvada is the only formulation of PrEP approved by the US Food and Drug Administration (FDA) for use in the United States in persons at risk of sexual acquisition of HIV infection. However, several studies reviewed by the USPSTF found that tenofovir disoproxil fumarate alone was also effective as PrEP, and CDC guidelines note that, given these trial data, tenofovir disoproxil fumarate alone can be considered as an alternative regimen for high-risk heterosexually active men and women and persons who inject drugs. [19, 20]
- I. The USPSTF recommends that clinicians offer to prescribe risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, to women who are at increased risk for breast cancer and at low risk for adverse medication effects. (B recommendation) The USPSTF recommends against the routine use of risk-reducing medications, such as tamoxifen, raloxifene, or aromatase inhibitors, in women who are not at increased risk for breast cancer. (D recommendation) This recommendation applies to asymptomatic women 35 years and older, including women with previous benign breast lesions on biopsy (such as atypical ductal or lobular hyperplasia and lobular carcinoma in situ). This recommendation does not apply to women who have a current or previous diagnosis of breast cancer or ductal carcinoma in situ.

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4 . Revision History

Date	Notes
11/1/2023	Addition of Apretude

Healthcare Reform Copay Waiver Review - Contraceptives

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Prior Authorization Guideline

Guideline ID	GL-133163
Guideline Name	Healthcare Reform Copay Waiver Review - Contraceptives

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	11/14/2019
P&T Revision Date:	10/18/2023

Note:

The intent of this policy is to allow patients to receive medications/products that are not on the Healthcare Reform (HCR) preventative drug list (but are in the same drug class) at no cost-share. First and foremost, the patient must meet the basic HCR criteria (as described below) in order to qualify for zero cost-share.

1 . Criteria

Product Name: Contraceptives [A]	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - For medical necessity requests, to waive cost-sharing for a medication not included on a zero cost-sharing coverage list* BOTH of the following must be met:

1.1 Patient is using the prescribed drug for contraception**

AND

1.2 The requested product is medically necessary***

Notes	*Zero cost share contraceptive coverage lists are available at: https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document . FDA Contraceptive Methods available at: https://www.fda.gov/consumers/free-publications-women/birth-control . **Benefit exclusion if not for contraception. ***Any justification of medical necessity/appropriateness provided by the prescriber is adequate to approve access of a preferred product at \$0 cost share, in accordance with the ACA's contraceptive mandate.
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2 . Endnotes

- A. Oral Contraceptives: In order to receive an oral contraceptive at zero cost-share, a woman must be of childbearing potential and must be requesting an oral contraceptive for contraception (and not for another use) or if provider states medical necessity (as well as meeting the other criteria noted at the beginning of the policy). In addition, the 21 or 28 day oral contraceptive packs should not be approved for continuous use because there are continuous use products already on the Healthcare Reform Preventative Drug List posted at:
<https://uhgazure.sharepoint.com/sites/CST/CSDM/Shared%20Documents/UMCS%20Guidelines/Healthcare%20Reform%20Supporting%20Document>.

3 . Revision History

Date	Notes
9/19/2023	Moved HCR Contraceptives criteria to its own guideline. No changes to criteria.

High Dollar/Claim Dollar

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Prior Authorization Guideline

Guideline ID	GL-133641
Guideline Name	High Dollar/Claim Dollar

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	3/26/2017
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/21/2021 ; 10/19/2022 ; 10/18/2023

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a High Dollar program. When a prescription exceeds the claim or high dollar threshold, the prescribed drug will be considered for coverage under the pharmacy benefit when the following criteria are met.

1 . Criteria

Product Name: A drug (non-anti-cancer chemotherapeutic regimen) used for an off-label indication or FDA approved indication	
Approval Length	12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file).
Guideline Type	Administrative

Approval Criteria

1 - One of the following:

1.1 Medication is being prescribed for an FDA-approved indication

OR

1.2 One of the following:

1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [1]

OR

1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [1]

OR

1.2.3 The use is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal**

AND

2 - One of the following:

2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

<p>2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:</p> <ul style="list-style-type: none"> American Hospital Formulary Service (AHFS) Compendium Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium 	
Notes	**May not apply to all benefit plans.

Product Name: A drug or biological in an anti-cancer chemotherapeutic regimen	
Approval Length	12 months, if no PA is on file. Approval duration is granted for length of current PA on file (if existing PA is on file).
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Medication is being prescribed for an FDA-approved indication</p> <p style="text-align: center;">OR</p> <p>1.2 One of the following:</p> <p>1.2.1 Diagnosis is supported as a use in American Hospital Formulary Service Drug Information (AHFS DI) [2]</p> <p style="text-align: center;">OR</p> <p>1.2.2 Diagnosis is supported in the FDA Uses/Non-FDA Uses section in DRUGDEX Evaluation with a Strength of Recommendation rating of IIb or better (see DRUGDEX Strength of Recommendation table in Background section) [2]</p> <p style="text-align: center;">OR</p> <p>1.2.3 Diagnosis is supported as a use in the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1,</p>	

2A, or 2B (see NCCN Categories of Evidence and Consensus table in Background section)
[2, B]

OR

1.2.4 Diagnosis is supported as an indication in Clinical Pharmacology [2]

OR

1.2.5 Off-label use is supported in one of the published, peer-reviewed medical literature listed below: [2, C]

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

OR

1.2.6 Diagnosis is supported as a use in Wolters Kluwer Lexi-Drugs rated as "Evidence

Level A" with a "Strong" recommendation. (see Lexi-Drugs Strength of Recommendation table in Background section) [2, 4, 5]

AND

2 - One of the following:

2.1 The dosage quantity/duration of the medication is reasonably safe and effective based on information contained in the FDA approved labeling, peer-reviewed medical literature, or accepted standards of medical practice

OR

2.2 The dosage/quantity/duration of the medication is reasonably safe and effective based on one of the following compendia:

- American Hospital Formulary Service (AHFS) Compendium
- Thomson Reuters (Healthcare) Micromedex/DrugDex (not Drug Points) Compendium
- Elsevier Gold Standard’s Clinical Pharmacology Compendium
- National Comprehensive Cancer Network Drugs and Biologics Compendium

Notes

**May not apply to all benefit plans.

2 . Background

Clinical Practice Guidelines		
DRUGDEX Strength of Recommendation [5]		
Class	Recommendation	Description
Class I	Recommended	The given test or treatment has been proven useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test or treatment is generally considered to be useful,

			and is indicated in most cases.
	Class IIb	Recommended, in Some Cases	The given test or treatment may be useful, and is indicated in some, but not most, cases.
	Class III	Not Recommended	The given test or treatment is not useful, and should be avoided
	Class Indeterminate	Evidence Inconclusive	

NCCN Categories of Evidence and Consensus [B]

Category	Level of Consensus
1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Lexi-Drugs: Strength of Recommendation for Inclusion in Lexi-Drugs for Oncology Off-Label Use and Level of Evidence Scale for Oncology Off-Label Use [5]

Strength of Recommendation for Inclusion

Strong (for proposed off-label use)	The evidence persuasively supports the off-label use (ie, Level of Evidence A).
Equivocal (for proposed off-label use)	The evidence to support the off-label use is of uncertain clinical significance (ie, Level of Evidence B, C). Additional studies may be necessary to further define the role of this

	medication for the off-label use.
Against proposed off-label use	The evidence either advocates against the off-label use or suggests a lack of support for the off-label use (independent of Level of Evidence). Additional studies are necessary to define the role of this medication for the off-label use.

Level of Evidence Scale for Oncology Off-Label Use

A	Consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form (eg, results of the introduction of penicillin treatment) to support off-label use. Further research is unlikely to change confidence in the estimate of benefit.
B	Evidence from randomized, controlled trials with important limitations (eg, inconsistent results, methodologic flaws, indirect, imprecise); or very strong evidence of some other research design. Further research (if performed) is likely to have an impact on confidence in the estimate of benefit and risk and may change the estimate.
C	Evidence from observational studies (eg, retrospective case series/reports providing significant impact on patient care); unsystematic clinical experience; or potentially flawed randomized, controlled trials (eg, when limited options exist for condition). Any estimate of effect is uncertain.
G	Use has been substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline.

3 . Endnotes

- A. OptumRx has high dollar criteria for clients who opt for such a program to help manage prescription costs. If the prescription cost exceeds the claim or high dollar threshold, then an administrative PA will be required. The pharmacist will review the prescription to see if it is in-line with FDA approved labeling or well supported by the approved compendia or a peer-reviewed medical journal.

- B. NCCN Categories of Evidence and Consensus. Category 1: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the NCCN Guideline Panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions. Category 2A: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so NCCN Guideline Panel Members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based judgments provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent. Category 2B: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data. Category 3: Including the recommendation has engendered a major disagreement among the NCCN Guideline Panel Members. The level of evidence is not pertinent in this category, because experts can disagree about the significance of high level trials. Several circumstances can cause major disagreements. For example, if substantial data exist about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. An example of this is the recommendation for internal mammary node radiation in postmastectomy radiation therapy. One side believed that because the randomized studies included this modality, it must be included in the recommendation. The other side believed, based on the documented additional morbidity and the role of internal mammary radiation therapy in other studies, that this was not necessary. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy. [3]
- C. Abstracts (including meeting abstracts) are excluded from consideration. When evaluating peer-reviewed medical literature, the following (among other things) should be considered: 1) Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence 2) Whether the administered chemotherapy regimen is adequately represented in the published evidence. 3) Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. 4) Whether the study is appropriate to address the clinical question. The following should be considered: a) Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); b) That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and c) That case reports are generally

considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs. [2]

4 . References

1. Center for Medicaid & Medicare Services. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Section 10.6. Available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. Accessed September 9, 2021.
2. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Chapter 15 - Covered Medical and Other Health Services. Section 50.4.5. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>. Accessed September 9, 2021.
3. National Comprehensive Cancer Network Categories of Evidence and Consensus. Available at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx. Accessed September 9, 2021.
4. Center for Medicaid & Medicare Services. Medicare Benefit Policy Manual. Wolters Kluwer Clinical Drug Information Lexi-Drugs Compendium Revision Request - CAG-004430. Available at: <https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31#decision>. Accessed September 9, 2021.
5. Wolters Kluwer Clinical Drug Information's Request for CMS evaluation of Lexi-Drugs as a compendium for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens. Available at: <https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/covdoc31.pdf>. Accessed September 9, 2021.
6. Micromedex Healthcare Series. Recommendation, Evidence and Efficacy Ratings. https://www.micromedexsolutions.com/micromedex2/librarian/ssl/true/CS/6E0ED9/ND_P R/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/8B9F5B/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/P FActionId/evidencexpert.IntermediateToDocumentLink?docId=3198&contentSetId=50. Accessed September 9, 2021.

5 . Revision History

Date	Notes
9/21/2023	2023 Annual Review. No changes to criteria.

IBS - Diarrhea



Prior Authorization Guideline

Guideline ID	GL-137433
Guideline Name	IBS - Diarrhea

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	1/13/2003
P&T Revision Date:	04/15/2020 ; 04/21/2021 ; 04/20/2022 ; 04/19/2023 ; 5/18/2023

1 . Indications

Drug Name: Lotronex (alosetron hydrochloride)
Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women Indicated only for women with severe diarrhea-predominant IBS who have: • chronic IBS symptoms (generally lasting 6 months or longer) • had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and • not responded adequately to conventional therapy. Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: • frequent and severe abdominal pain/discomfort • frequent bowel urgency or fecal incontinence • disability or restriction of daily activities due to IBS. Because of infrequent but serious gastrointestinal adverse reactions associated with Lotronex, the indication is restricted to those patients for whom the benefit-to-risk balance is most favorable. Clinical studies have not been performed to adequately confirm the benefits of Lotronex in men.
Drug Name: Viberzi (eluxadoline)
Irritable bowel syndrome with diarrhea (IBS-D) Indicated in adults for the treatment of IBS-D.

2 . Criteria

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	12 Week(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS)</p> <p style="text-align: center;">AND</p> <p>2 - Symptoms for at least 6 months [A]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is female</p> <p style="text-align: center;">AND</p> <p>4 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>5 - Trial and failure, contraindication, or intolerance to both of the following:</p> <ul style="list-style-type: none"> • antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6, B] • antidiarrheal agent [eg, loperamide] [2, 3, 6] 	

Product Name: Brand Lotronex, Generic alosetron	
Approval Length	6 month(s)

Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Symptoms of IBS continue to persist</p> <p style="text-align: center;">AND</p> <p>2 - Patient demonstrates positive clinical response to therapy as evidenced by one of the following: [1]</p> <ul style="list-style-type: none"> • Relief of IBS abdominal pain and discomfort • Improvement in stool consistency • Decrease in daily stool frequency • Moderate or substantial improvement as measured by the Global Improvement Scale [C] 	

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of irritable bowel syndrome with diarrhea</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to both of the following:</p> <ul style="list-style-type: none"> • antispasmodic agent [eg, Bentyl (dicyclomine)] [2, 6] • antidiarrheal agent [eg, Lomotil (diphenoxylate and atropine)] [2, 3, 6] 	

Product Name: Viberzi	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Symptoms of IBS continue to persist</p> <p style="text-align: center;">AND</p> <p>2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [D]</p> <ul style="list-style-type: none"> • Improvement in the daily worst abdominal pain score • Reduction in the Bristol Stool Scale 	

3 . Endnotes

- A. Lotronex was removed from the market in late 2000 due to reports of ischemic colitis and severe constipation but has since been re-released with a “black box” warning for use in select cases. [1, 3, 4, 5]
- B. Lotronex should be used with caution in debilitated patients, elderly patients, patients with hepatic impairment, and patients taking medications that decrease gastrointestinal motility. [1]
- C. The Global Improvement Scale (GIS) assesses multiple symptoms of Irritable Bowel Syndrome (IBS) using a 7-point Likert scale which ranges from symptoms substantially worse to substantially improved. GIS responders were defined as having moderate or substantial improvement in IBS symptoms. [1]
- D. The primary endpoint in Studies 1 and 2 to assess the efficacy of Viberzi was defined by both the simultaneous improvement in the daily worse abdominal pain score by $\geq 30\%$ as compared to the baseline weekly average AND a reduction in the BSS to < 5 on at least 50% of the days within a 12-week time interval. [7]

4 . References

1. Lotronex Prescribing Information. Sebela Pharmaceuticals Inc. Roswell, Georgia, CA. July 2016.
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3. Wilkins T, Pepitone C, Alex B, Schade RR. Diagnosis and management of IBS in adults. *Am Fam Physician*. 2012;86(5):419-26.
4. Camiller M, Mayer EA, Drossman DA, et al. Improvement in the pain and bowel function in female irritable bowel patients with alosetron, a 5-HT₃ antagonist. *Aliment Pharmacol Ther* 1999;13(9):1149-5.
5. Chey WD, Chey WY, Health AT, et al. Long-term Safety and Efficacy of Alosetron in Women with Severe Diarrhea-Predominant Irritable Bowel Syndrome. *Am J of Gastroenterol* 2004;99:2195-2203.
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7. Viberzi Prescribing Information. Allergan USA, Inc. Madison, NJ. June 2020.
8. Alosetron Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. January 2016
9. Ford AC, Moayyedi P, Chey WD, Harris LA, Lacy BE, Saito YA, Quigley EMM; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2018 Jun;113(Suppl 2):1-18.

5 . Revision History

Date	Notes
12/6/2023	Update reauth verbiage

Inhaled Corticosteroids

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Prior Authorization Guideline

Guideline ID	GL-136645
Guideline Name	Inhaled Corticosteroids

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/18/2015
P&T Revision Date:	03/18/2020 ; 10/21/2020 ; 03/17/2021 ; 03/16/2022 ; 03/15/2023 ; 11/16/2023 ; 12/13/2023

1 . Indications

Drug Name: Alvesco (ciclesonide) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older. Important Limitations of Use: Alvesco is NOT indicated for the relief of acute bronchospasm or for children under 12 years of age.
Drug Name: ArmonAir Digihaler (fluticasone propionate) Inhalation Powder
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Limitations of Use: ArmonAir Digihaler is not indicated for the relief of acute bronchospasm.
Drug Name: Asmanex HFA (mometasone furoate) Inhalation Aerosol
Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. Important Limitations of Use: Asmanex HFA is NOT indicated for the relief of acute bronchospasm.
Drug Name: Asmanex (mometasone furoate) Inhalation Powder

<p>Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older. Limitations of Use: Asmanex Twisthaler is NOT indicated for the relief of acute bronchospasm or in children less than 4 years of age.</p>
<p>Drug Name: Flovent (fluticasone propionate aerosol) HFA</p>
<p>Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients aged 4 years and older. Limitations of Use FLOVENT HFA is not indicated for the relief of acute bronchospasm.</p>
<p>Drug Name: Flovent (fluticasone propionate powder) Diskus</p>
<p>Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients aged 4 years and older. Important Limitation of Use FLOVENT DISKUS is NOT indicated for the relief of acute bronchospasm.</p>
<p>Drug Name: Pulmicort (budesonide aerosol) Flexhaler</p>
<p>Asthma Indicated for the maintenance treatment of asthma as prophylactic therapy in patients six years of age or older. Limitations of Use: PULMICORT FLEXHALER is NOT indicated for the relief of acute bronchospasm.</p>

2 . Criteria

<p>Product Name: Armonair Digihaler*, Alvesco*, Asmanex HFA*, Asmanex Twisthaler*, Flovent Diskus, Flovent HFA, Pulmicort Flexhaler, Brand Fluticasone Propionate Diskus</p>	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to both of the following preferred brands:</p> <ul style="list-style-type: none"> • Arnuity Ellipta 	

<ul style="list-style-type: none"> QVAR Redihaler 	
Notes	*Product may be excluded depending on the plan.

Product Name: Brand Fluticasone Propionate HFA	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Trial and failure, contraindication, or intolerance to both of the following preferred brands:</p> <ul style="list-style-type: none"> Arnuity Ellipta QVAR Redihaler <p style="text-align: center;">OR</p> <p>2.2 Patient is 5 years of age or less and requires a spacer with the meter dose inhaler [A, 9]</p>	

3 . Endnotes

- A. Dry powder inhalers are not suitable for most children ≤ 5 years of age and some elderly patients; pressurized metered dose inhalers with spacers remain essential for such patients. [9]

4 . References

- Alvesco [prescribing information]. Zug 6300, Switzerland: Covis Pharma; February 2023.

2. ArmonAir Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
3. Asmanex [prescribing information]. Jersey City, NJ: Organon LLC; June 2021.
4. Asmanex HFA [prescribing information]. Jersey City, NJ: Organon LLC; March 2023.
5. Flovent HFA Prescribing Information. GlaxoSmithKline. Durham, NC. September 2023.
6. Flovent Diskus Prescribing Information. GlaxoSmithKline. Durham, NC. August 2023.
7. Pulmicort Flexhaler Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington DE. October 2019.
8. Fluticasone Propionate Diskus Prescribing Information. Prasco Laboratories Mason OH. May 2023.
9. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention 2023. Updated July 2023. Available from www.ginaasthma.org

5 . Revision History

Date	Notes
12/14/2023	Addition of Fluticasone Propionate Diskus as target to guideline. Updated criteria for brand Fluticasone HFA to allow a bypass of the trial of Arnuity Ellipta and Qvar Redihaler for pediatric patients who require use of a spacer with their meter dose inhalers.

Insomnia Agents



Prior Authorization Guideline

Guideline ID	GL-133702
Guideline Name	Insomnia Agents

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	2/18/2015
P&T Revision Date:	09/18/2019 ; 09/16/2020 ; 09/15/2021 ; 09/21/2022 ; 10/19/2022 ; 06/21/2023 ; 09/20/2023

1 . Indications

Drug Name: Edluar (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. The clinical trials performed with zolpidem tartrate in support of efficacy were 4-5 weeks in duration with the final formal assessments of sleep latency performed at the end of treatment.
Drug Name: Ambien (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation.
Drug Name: Ambien CR (zolpidem tartrate)
Insomnia Indicated for the short-term treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Quviviq (daridorexant)

Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance in adults.
Drug Name: Belsomra (suvorexant)
Insomnia Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Dayvigo (lemborexant)
Insomnia Indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.
Drug Name: Zolpidem tartrate capsule
Insomnia Indicated for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than 65 years of age.

2 . Criteria

Product Name: Ambien, Ambien CR, Brand Zolpidem capsules, Edluar	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), or intolerance to one of the following:</p> <ul style="list-style-type: none"> • zolpidem • zolpidem ER 	

Product Name: Quviviq

Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - ONE of the following:</p> <p>2.1 If the patient is less than 65 years of age, BOTH of the following:</p> <p>2.1.1 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> • Belsomra* • Dayvigo* <p style="text-align: center;">AND</p> <p>2.1.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:</p> <ul style="list-style-type: none"> • eszopiclone • zaleplon • zolpidem • zolpidem ER • triazolam • temazepam • generic ramelteon • doxepin <p style="text-align: center;">OR</p> <p>2.2 If the patient is 65 years of age and older, trial and failure (of a minimum 30-day supply), contraindication, or intolerance to TWO of the following:</p> <ul style="list-style-type: none"> • generic ramelteon 	

<ul style="list-style-type: none"> • Belsomra* • Dayvigo* • doxepin 	
Notes	*NOTE: Step Therapy (ST) requirements may apply for brand Belsomra and brand Dayvigo

Product Name: Belsomra, Dayvigo	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> • doxepin • eszopiclone • temazepam • zaleplon • zolpidem • zolpidem ER 	

3 . References

1. Edluar Prescribing Information. Meda Pharmaceuticals Inc. Somerset, NJ. August 2022.
2. Ambien Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
3. Ambien CR Prescribing Information. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. February 2022.
4. Quviviq Prescribing Information. Idorsia Pharmaceuticals US Inc. Radnor, PA. April 2023.
5. Belsomra Prescribing Information. Merck Sharp & Dohme LLC. Rahway, NJ. February 2023.
6. Dayvigo Prescribing Information. Eisai Inc. Nutley, NJ. May 2023.

7. The 2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc 00:1-21, 2019. Available at <https://www.uclahealth.org/geriatrics/workfiles/education/clinical-skills/handouts/Education-Updated-Beers-List-2019.pdf>. Accessed August 7, 2023.
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10. Zolpidem Prescribing Information. Almatica Pharma LLC. Morristown, NJ. May 2023.

4 . Revision History

Date	Notes
9/22/2023	Background update (indications).

Insulin Delivery Systems



Prior Authorization Guideline

Guideline ID	GL-125350
Guideline Name	Insulin Delivery Systems

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	6/23/2009
P&T Revision Date:	09/15/2021 ; 06/15/2022 ; 6/21/2023

Note:

This guideline applies to plans that only provide coverage for insulin vials. The intent of this policy is to serve as guidance for clients who would like to allow for exceptions reviews for excluded insulin delivery systems.

1 . Criteria

Product Name: Insulin dosers, cartridges, or pen devices	
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - Will be approved, except when excluded as a plan benefit, based on one of the following criteria:</p>	

1.1 The patient has visual impairment (unable to use insulin vial and syringe)

OR

1.2 The patient has physical impairment (unable to use insulin vial and syringe)

2 . Revision History

Date	Notes
5/25/2023	2023 Annual Review

Intrarosa (prasterone)

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Prior Authorization Guideline

Guideline ID	GL-125555
Guideline Name	Intrarosa (prasterone)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	7/21/2021
P&T Revision Date:	06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Intrarosa (prasterone)
Moderate to Severe Dyspareunia Indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause.

2 . Criteria

Product Name: Intrarosa	
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 28-day supply), contraindication, or intolerance to one of the following:

- Premarin vaginal cream
- Osphena

3 . References

1. Intrarosa prescribing information. AMAG Pharmaceuticals, Inc. Waltham, MA. February 2018.

4 . Revision History

Date	Notes
5/10/2023	2023 UM Annual Review. Updated trial duration to 28 days supply

Leukotriene Modifiers

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Prior Authorization Guideline

Guideline ID	GL-121023
Guideline Name	Leukotriene Modifiers

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	8/21/1998
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Zileuton extended-release
Asthma Indicated for the prophylaxis and chronic treatment of asthma in adults and children 12 years of age and older. Zileuton extended-release tablet is not indicated for use in the reversal of bronchospasm in acute asthma attacks. Therapy with zileuton extended-release tablet can be continued during acute exacerbations of asthma.

2 . Criteria

Product Name: Generic zileuton ER	
Diagnosis	Asthma
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, intolerance, or contraindication to at least one of the following generics:

- montelukast
- zafirlukast

3 . References

1. Zileuton Extended-Release [prescribing information]. Baltimore, MD: Lupin Pharmaceuticals, Inc; August 2020

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Long Acting Insulins

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Prior Authorization Guideline

Guideline ID	GL-125389
Guideline Name	Long Acting Insulins

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	7/21/2021
P&T Revision Date:	06/15/2022 ; 02/16/2023 ; 6/21/2023

1 . Indications

Drug Name: Levemir (insulin detemir)
Diabetes Mellitus Indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus. Limitations of Use: Levemir is not recommended for the treatment of diabetic ketoacidosis.
Drug Name: Tresiba (insulin degludec)
Diabetes Mellitus Indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus. Limitations of Use: Not recommended for the treatment of diabetic ketoacidosis.

2 . Criteria

Product Name: Levemir, Tresiba

Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of diabetes mellitus</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure of a minimum 30 days supply, contraindication, or intolerance to one of the following:</p> <ul style="list-style-type: none"> • Lantus • Toujeo 	

3 . References

1. Levemir Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. December 2022.
2. Tresiba Prescribing Information. Novo Nordisk Inc. Plainsboro, New Jersey. July 2022.

4 . Revision History

Date	Notes
5/25/2023	2023 Annual Review - updated references

Long-Acting Bronchodilator Combinations



Prior Authorization Guideline

Guideline ID	GL-121072
Guideline Name	Long-Acting Bronchodilator Combinations

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/20/2019
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Bevespi Aerosphere (glycopyrrolate and formoterol fumarate)
Chronic Obstructive Pulmonary Disease (COPD) Indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Limitations of use: Bevespi Aerosphere is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

2 . Criteria

Product Name: Bevespi	
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, contraindication, or intolerance to any one of the following generics or preferred brands:

- Advair HFA
- Breo Ellipta
- fluticasone/salmeterol
- Serevent
- Symbicort
- Wixela Inhub

AND

3 - Trial and failure, contraindication, or intolerance to Spiriva

3 . References

1. Bevespi Aerosphere [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2020.

4 . Revision History

Date	Notes
2/22/2023	2023 UM Annual Review. No changes

Migraine Quantity Limit

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Prior Authorization Guideline

Guideline ID	GL-131835
Guideline Name	Migraine Quantity Limit

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	5/19/2016
P&T Revision Date:	03/18/2020 ; 03/17/2021 ; 03/16/2022 ; 04/20/2022 ; 04/19/2023 ; 08/17/2023

1 . Indications

Drug Name: Amerge (naratriptan), Frova (frovatriptan), Imitrex (sumatriptan) tablets and nasal spray, Onzetra (sumatriptan), Relpax (eletriptan), Tosymra (sumatriptan), Zembrace SymTouch (sumatriptan), Zomig (zolmitriptan) tablets, Zomig-ZMT (zolmitriptan)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Safety and effectiveness of respective triptan therapy have not been established for cluster headache (not applicable to Zembrace SymTouch). Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with therapy, reconsider the diagnosis of migraine before therapy is administered to treat any subsequent attacks. Therapy is not indicated for the prevention of migraine attacks.

Drug Name: Axert (almotriptan)

Migraine Headaches Indicated for the acute treatment of migraine attacks in adults with a history of migraine with or without aura. Indicated for the acute treatment of migraine headache pain in adolescents age 12 to 17 years with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated). Important Limitations: Only use

where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Drug Name: Maxalt (rizatriptan), Maxalt-MLT (rizatriptan)

Migraine headaches Indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of Use: Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Drug Name: Migranal (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine headaches with or without aura. Not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine.

Drug Name: Treximet (sumatriptan/naproxen)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age or older. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Drug Name: Zomig (zolmitriptan) nasal spray

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older. Limitations of Use: Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Drug Name: D.H.E. 45 (dihydroergotamine mesylate) injection

Migraine Headache Indicated for the acute treatment of migraine headaches with or without aura.

Cluster Headaches Indicated for acute treatment of cluster headache episodes.

Drug Name: Imitrex (sumatriptan) injection

Migraine Headache Indicated in adults for the acute treatment of migraine, with or without aura. Limitations of Use: Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of migraine headache attacks.

Cluster Headaches Indicated in adults for the acute treatment of cluster headache. Limitations of Use: Use only if a clear diagnosis of cluster headache has been established. If a patient has no response to the first cluster headache attack treated with Imitrex injection, reconsider the diagnosis before Imitrex injection is administered to treat any subsequent attacks. Imitrex injection is not indicated for the prevention of cluster headache attacks.

Drug Name: Trudhesa (dihydroergotamine mesylate)

Migraine Headaches Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine or for the management of hemiplegic or basilar migraine

Drug Name: Nurtec ODT (rimegepant sulfate)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults.

Preventive Treatment of Episodic Migraine Indicated for the preventive treatment of episodic migraine in adults.

Drug Name: Ubrelvy (ubrogepant)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

Drug Name: Zavzpret (zavegepant)

Acute Treatment of Migraine Indicated for the acute treatment of migraine with or without aura in adults. Limitations of Use: Not indicated for the preventive treatment of migraine.

2 . Criteria

Product Name: Brand Amerge, Generic naratriptan, Brand Axert, Generic almotriptan, Brand Frova, Generic frovatriptan, Brand Imitrex, Generic sumatriptan, Brand Maxalt, Generic rizatriptan, Onzetra, Brand Relpax, Generic eletriptan, Tosymra, Brand Treximet, Generic sumatriptan/naproxen, Zembrace SymTouch, Brand Zomig, Generic zolmitriptan, or Brand Zolmitriptan nasal spray	
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Patient is experiencing 2 or more headaches per month [10-12]</p> <p style="text-align: center;">AND</p> <p>3 - Patient will not be treating 15 or more headache days per month</p> <p style="text-align: center;">AND</p> <p>4 - Currently receiving prophylactic therapy with at least one of the following: [A, 10, 25]</p> <ul style="list-style-type: none"> • An antidepressant (i.e., Elavil [amitriptyline] or Effexor [venlafaxine]) • An anticonvulsant (i.e., Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate]) • A beta-blocker (i.e., atenolol, propranolol, nadolol, timolol, or metoprolol) • An angiotensin receptor blocker (i.e., Atacand [candesartan]) • An angiotensin-converting enzyme (ACE) inhibitor (i.e., lisinopril) <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> • Neurologist 	

<ul style="list-style-type: none"> • Pain specialist • Headache specialist [B] <p style="text-align: center;">AND</p> <p>6 - Not used in combination with another triptan-containing product</p> <p style="text-align: center;">AND</p> <p>7 - One of the following: [C]</p> <p>7.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer’s prescribing information</p> <p style="text-align: center;">OR</p> <p>7.2 Higher dose or quantity is supported by one of the following compendia:</p> <ul style="list-style-type: none"> • American Hospital Formulary Service Drug Information • Micromedex DRUGDEX System

Product Name: Brand D.H.E. 45, Generic dihydroergotamine mesylate injection, Brand Migranal, Generic dihydroergotamine mesylate nasal spray, Nurtec ODT, Trudhesa, Ubrelvy, Zavzpret	
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - One of the following: [C]</p>	

2.1 Higher dose or quantity is supported in the Dosage and Administration section of the manufacturer’s prescribing information

OR

2.2 Higher dose or quantity is supported by one of the following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

3 . Endnotes

- A. The American Academy of Neurology and American Headache Society support the use of the following medications for the prevention of episodic migraine in adult patients (with level A or B evidence): antidepressants [i.e., Elavil (amitriptyline), Effexor (venlafaxine)], antiepileptics [i.e., Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [i.e., atenolol, propranolol, nadolol, timolol, metoprolol], and candesartan. [10, 25]
- B. Headache specialists are physicians certified by the United Council for Neurologic Subspecialties (UCNS). [24]
- C. Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.

4 . References

1. Amerge Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. October 2020.
2. Almotriptan Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. May 2017.
3. Frova Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2018.
4. Imitrex Tablets Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2020.
5. Imitrex Nasal Spray Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2017.
6. Imitrex Injection Prescribing Information. GlaxoSmithKline. Research Triangle Park, NC. December 2021.
7. Maxalt/Maxalt MLT Prescribing Information. Organon LLC. Jersey City, NJ. June 2021.
8. Migranal Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2022.
9. Relpax Prescribing Information. Roerig. New York, NY. March 2020.

10. Silberstein SD, Holland S, Freitag F, et al. Evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2012;78:1337-1345.
11. Silberstein SD, Holland S, Freitag F, et al. Erratum to: evidence-based guideline update: pharmacologic treatment for episodic migraine prevention in adults: report of the Quality Standards Subcommittee of the American Academy of Neurology and the American Headache Society. *Neurology*. 2013;80(9):871.
12. Snow V, Weiss K, Wall EM, Mottur-Pilson C; American Academy of Family Physicians; American College of Physicians-American Society of Internal Medicine. Pharmacologic management of acute attacks of migraine and prevention of migraine headache. *Ann Intern Med*. 2002;137:840-9.
13. Onzetra Xsail Prescribing Information. Currax Pharmaceuticals LLC. Morristown, NJ. December 2019.
14. Treximet Prescribing Information. Currax Pharmaceuticals LLC. Brentwood, TN. October 2021.
15. Zomig/Zomig ZMT Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
16. Zomig Nasal Spray Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. May 2019.
17. D.H.E. 45 Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. April 2022.
18. Loder E, Burch R, Rizzoli P. The 2012 AHS/AAN Guidelines for Prevention of Episodic Migraine: A Summary and Comparison with Other Recent Clinical Practice Guidelines. *Headache* 2012;52:930-945.
19. Zembrace SymTouch Prescribing Information. Promius Pharma, LLC. Princeton, NJ. June 2019.
20. Tosymra Prescribing Information. Promius Pharma, LLC. Princeton, NJ. January 2019.
21. Trudhesa Prescribing Information. Impel NeuroPharma Inc. Seattle, WA. September 2021.
22. Nurtec ODT Prescribing Information. Biohaven Pharmaceuticals, Inc. New Haven, CT. April 2022.
23. Ubrelvy Prescribing Information. Allergan USA, Inc. Madison, NJ. March 2021.
24. United Council for Neurologic Subspecialties website. www.ucns.org. Accessed February 13, 2023.
25. AHS Consensus Statement. Update on integrating new migraine treatments into clinical practice. *Headache*. 2021 Jul;61(7):1021-1039.

5 . Revision History

Date	Notes
8/28/2023	Removal of drug name, Sumavel Dosepro, from header in criteria section.

Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)



Prior Authorization Guideline

Guideline ID	GL-135828
Guideline Name	Nexletol (bempedoic acid) and Nexlizet (bempedoic acid-ezetimibe)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/14/2020
P&T Revision Date:	05/20/2021 ; 05/19/2022 ; 05/18/2023 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Nexletol (bempedoic acid), Nexlizet (bempedoic acid-ezetimibe)
HeFH or ASCVD Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C. Limitations of Use: The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined.

2 . Criteria

Product Name: Nexletol, Nexlizet	
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [11]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization (e.g., percutaneous coronary intervention [PCI] or coronary artery bypass graft [CABG] surgery)
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of one HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of one MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin

40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of one LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low-, moderate-, or high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [C]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following LDL-C values while on maximally tolerated statin therapy within the last 120 days: [6-9]

- LDL-C greater than or equal to 55 mg/dL with ASCVD
- LDL-C greater than or equal to 100 mg/dL without ASCVD

AND

4 - One of the following: [D]

4.1 Patient has been receiving at least 12 consecutive weeks of generic ezetimibe therapy as adjunct to maximally tolerated statin therapy [A]

OR

4.2 Patient has a history of contraindication or intolerance to ezetimibe

Product Name: Nexletol, Nexlizet	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., reduction in LDL-C levels)</p> <p>AND</p> <p>2 - One of the following:</p> <p>2.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose</p> <p>OR</p> <p>2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)</p>	

3 . Endnotes

- A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [5]
- B. In the Nexletol and Nexlizet pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-4]
- C. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [5]
- D. The effect of bempedoic acid on cardiovascular morbidity and mortality has not been determined. Outcomes trials evaluating the efficacy of bempedoic acid are currently underway. In contrast, IMPROVE-IT was a prospective randomized controlled trial evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit modestly (HR 0.936; 95% CI 0.887, 0.988; p = 0.016; number needed to treat [NNT] = 50). The 2017 ACC/AHA non-statin decision pathway update recommends that for patients who are maximized on statin therapy with baseline LDL-C 70-189 mg/dL, it is reasonable to consider the addition of ezetimibe. In patients with clinical ASCVD who are judged to be very high risk with LDL-C 70 mg/dL or higher, maximally tolerated LDL-C lowering therapy should include maximally tolerated statin therapy and ezetimibe. [5, 8-9]

4 . References

1. Nexletol Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. February 2020.
2. Nexlizet Prescribing Information. Esperion Therapeutics, Inc. Ann Arbor, MI. November 2020.
3. WHO Familial Hypercholesterolemia Consultation Group. Familial Hypercholesterolemia (FH): report of a second WHO consultation. Geneva: World Health Organization; 1999.
4. Scientific Steering Committee on behalf of the Simon Broome Register Group. Risk of fatal coronary heart disease in familial hypercholesterolemia. *BMJ*. 1991;303:893-6.
5. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol* 2019; 73:e285-e350.
6. ATP III Final Report PDF. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) Final Report. *Circulation*. 2002;106:3143-3421.
7. Per clinical drug consult with cardiologist. August 3, 2015.
8. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2017 Focused Update of the 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk. *J Am Coll Cardiol*. 2017;70:1785-1822.
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11. Per clinical drug consult with cardiologist. November 17, 2017.

5 . Revision History

Date	Notes
11/2/2023	Program update to standard reauthorization language. No changes to clinical intent.

Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern



Prior Authorization Guideline

Guideline ID	GL-137282
Guideline Name	Non-Formulary & Excluded Drug Exceptions Process for Drugs of Clinical Concern

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/19/2013
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 03/18/2020 ; 04/15/2020 ; 05/14/2020 ; 07/15/2020 ; 07/15/2020 ; 11/12/2020 ; 03/17/2021 ; 03/17/2021 ; 06/16/2021 ; 11/18/2021 ; 12/15/2021 ; 01/19/2022 ; 11/17/2022 ; 06/21/2023 ; 11/16/2023

Note:

The purpose of this guideline is to establish policies and procedures on how to handle non-formulary and excluded drugs when continuation of prior therapy is allowed. This guideline will not apply to drug exclusions that do not allow for continuation of prior therapy, drugs with step therapy edits, drugs that require quantity limit review only, or drugs that are not reviewed for prior authorization by OptumRx. ** Please consult client-specific resources to confirm whether benefit exclusions should be reviewed for medical necessity.**

1 . Criteria

Product Name: Aplenzin, Aptiom, Brand Atripla, Auvelity, Ayvakit, Brukinsa, Caplyta, Brand Combivir, Delstrigo, Generic efavirenz-lamivudine-tenofovir DF, Brand Emtriva capsules, Brand Epivir, Brand Epzicom, Esperoct, Fintepla, Forfivo XL, Bupropion HCL 450mg ER (XL), Brand Genvoya, Ilumya, Brand Intelence, Jivi, Brand Kaletra, Kcentra, Brand Lexiva, Lybalvi,

<p>Mononine, Brand Norvir tablets, Nubeqa, Nuplazid, Oxtellar XR, Rebinyn, Brand Retrovir, Rexulti, Brand Reyataz capsules, Savaysa, Siliq, Spritam, Stribild, Brand Sustiva, Brand Symfi, Brand Symfi Lo, Brand Trizivir, Trogarzo, Trokendi XR, Brand Viramune XR, Brand Viread tablets, Xeljanz oral solution, Xembify, Brand Ziagen, Zykadia</p>	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 One of the following:</p> <p>1.1.1 Patient has failed or has contraindications or intolerance to at least three equivalent formulary drugs. If only one or only two equivalents are available, the patient must have failed or had contraindications or intolerance to all available equivalent formulary drugs. The clinician's judgment should be used to determine equivalent formulary drugs for the indication provided. (Refer to Table 1 for examples of equivalent formulary drugs)</p> <p style="text-align: center;">OR</p> <p>1.1.2 No formulary drug is appropriate to treat the patient's condition</p> <p style="text-align: center;">AND</p> <p>1.2 One of the following:</p> <p>1.2.1 Both of the following:</p> <p>1.2.1.1 Requested drug is FDA-approved for the condition being treated</p> <p style="text-align: center;">AND</p> <p>1.2.1.2 Additional requirements listed in the "Indications and Usage" sections of the prescribing information (or package insert) have been met (e.g., first line therapies have been tried and failed, any testing requirements have been met, etc.)</p> <p style="text-align: center;">OR</p>	

1.2.2 If requested for an off-label indication, the off-label guideline approval criteria have been met

OR

2 - For continuation of prior therapy

2 . Background

Benefit/Coverage/Program Information		
Table 1. Formulary Alternatives for Exclusion Drugs of Clinical Concern		
Therapeutic Category	Excluded Medication	Preferred Formulary Alternatives (*May require PA)
Anticonvulsants	Fintepla (fenfluramine)	<ul style="list-style-type: none"> Valproic acid or clobazam Diacomit (stiripentol)*, cannabidiol*, lamotrigine, topiramate, zonisamide, levetiracetam, Briviactam (brivaracetam)*
Anticonvulsants	Trokendi XR (topiramate extended-release)	<ul style="list-style-type: none"> Generic anticonvulsants: lamotrigine, topiramate, levetiracetam, oxcarbazepine, carbamazepine)
Anticonvulsants	Oxtellar XR (oxcarbazepine extended-release)	<ul style="list-style-type: none"> Generic anticonvulsants: lamotrigine, topiramate, levetiracetam, oxcarbazepine, carbamazepine)
Anticonvulsants	Aptiom (eslicarbazepine)	<ul style="list-style-type: none"> Generic oxcarbazepine

<p>Antidepressants</p>	<p>Aplenzin (bupropion hydrobromide extended-release)</p> <p>Forfivo XL (bupropion hydrochloride extended-release)</p>	<ul style="list-style-type: none"> • Generic bupropion XL products
<p>Antidepressants</p>	<p>Auvelity (Dextromethorphan HBR-Bupropion HCL TAB ER 45-105 MG)</p>	<ul style="list-style-type: none"> • generic bupropion • generic citalopram • generic desvenlafaxine • generic escitalopram • generic fluoxetine • generic mirtazapine • generic paroxetine • generic sertraline • generic venlafaxine
<p>Antipsychotics, Atypical</p>	<p>Caplyta (lumateperone)</p>	<ul style="list-style-type: none"> • Generic atypical antipsychotics (e.g., aripiprazole, generic asenapine sublingual tablet, clozapine, olanzapine, paliperidone, quetiapine IR/ER, risperidone, ziprasidone)
<p>Antivirals</p>	<p>Atripla (efavirenz-emtricitabine-tenofovir DF)</p>	<ul style="list-style-type: none"> • Generic efavirenz-emtricitabine-tenofovir df • Symfi (efavirenz-lamivudine-tenofovir DF) • Symfi Lo (efavirenz-lamivudine-tenofovir DF) • Triumeq (abacavir-dolutegravir-lamivudine) • Juluca (dolutegravir-ralpivirine) • Cimduo (lamivudine-tenofovir DF) plus Isentress (raltegravir) • Cimduo (lamivudine-tenofovir DF) plus Tivicay (dolutegravir)

Antivirals	Reyataz (atazanavir sulfate) capsules	<ul style="list-style-type: none"> • Generic atazanavir sulfate capsules
Antivirals	Lexiva (fosamprenavir calcium)	<ul style="list-style-type: none"> • Generic fosamprenavir calcium
Antivirals	Norvir (ritonavir) tablets	<ul style="list-style-type: none"> • Generic ritonavir tablets
Antivirals	Ziagen (abacavir sulfate)	<ul style="list-style-type: none"> • Generic abacavir sulfate
Antivirals	Emtriva (emtricitabine) capsules	<ul style="list-style-type: none"> • Generic emtricitabine capsules
Antivirals	Epivir (lamivudine)	<ul style="list-style-type: none"> • Generic lamivudine
Antivirals	Retrovir (zidovudine)	<ul style="list-style-type: none"> • Generic zidovudine
Antivirals	Viread (tenofovir disoproxil fumarate) tablets	<ul style="list-style-type: none"> • Generic tenofovir disoproxil fumarate tablets
Antivirals	Sustiva (efavirenz)	<ul style="list-style-type: none"> • Generic efavirenz
Antivirals	Intelence (etravirine) 100 mg, 200 mg	<ul style="list-style-type: none"> • Generic etravirine
Antivirals	Viramune XR (nevirapine)	<ul style="list-style-type: none"> • Generic nevirapine ER
Antivirals	Epzicom (abacavir sulfate-lamivudine)	<ul style="list-style-type: none"> • Generic abacavir sulfate-lamivudine
Antivirals	Combivir (lamivudine-zidovudine)	<ul style="list-style-type: none"> • Generic lamivudine-zidovudine
Antivirals	Kaletra (lopinavir-ritonavir)	<ul style="list-style-type: none"> • Generic lopinavir-ritonavir
Antivirals	Trizivir (abacavir sulfate-lamivudine-zidovudine)	<ul style="list-style-type: none"> • Generic abacavir sulfate-lamivudine-zidovudine
Antivirals	Delstrigo (doravirine-lamivudine-tenofovir df)	<ul style="list-style-type: none"> • No alternative available
Antivirals	Symfi (efavirenz-lamivudine-tenofovir df), Symfi Lo (efavirenz-lamivudine-tenofovir df)	<ul style="list-style-type: none"> • Generic efavirenz-lamivudine-tenofovir df
Antivirals	Genvoya (elvitegravir-cobicistat-emtricitabine-tenofovir alafenamide)	<ul style="list-style-type: none"> • No alternative available
Antivirals	Stribild (elvitegravir-cobicistat-emtricitabine-tenofovir df)	<ul style="list-style-type: none"> • No alternative available
Antivirals	Trogarzo (ibalizumab injection)	<ul style="list-style-type: none"> • No alternative available

Central Nervous System	Lybalvi (olanzapine and samidorphan)	<ul style="list-style-type: none"> • generic aripiprazole • generic asenapine • generic clozapine • generic olanzapine • generic paliperidone • generic quetiapine IR/ER • generic risperidone • generic ziprasidone
Hemophilia Agents	Esperoct (antihemophilic factor [recombinant], glycopegylated-exei) Jivi (antihemophilic factor [recombinant], pegylated-aucl)	<ul style="list-style-type: none"> • Adynovate (antihemophilic factor [recombinant] pegylated) • Afstyla (antihemophilic factor [recombinant], single chain) • Eloctate (antihemophilic factor [recombinant], Fc fusion protein)
Immunological Agents	Xembify [immune globulin subcutaneous (human)- klhw]	<ul style="list-style-type: none"> • Cuvitru [immune globulin (human)]*
Immunomodulators	Ilumya (tildrakizumab-asmn) Siliq (brodalumab)	<ul style="list-style-type: none"> • Taltz (ixekizumab)* • Cimzia (certolizumab pegol)* • Humira (adalimumab)* • Skyrizi (risankizumab)* • Stelara (ustekinumab)* • Tremfya (guselkumab)*
Immunomodulators	Xeljanz (tofacitinib) oral solution	<ul style="list-style-type: none"> • Humira (adalimumab)*
Oncology Agents	Zykadia (ceritinib)	<ul style="list-style-type: none"> • Alecensa (alectinib)* • Alunbrig (brugatinib)*
Oncology Agents	Brukinsa (zanubrutinib)	<ul style="list-style-type: none"> • No alternative available

3 . Revision History

Date	Notes
12/1/2023	Background updates.

Non-formulary Descovy and Truvada



Prior Authorization Guideline

Guideline ID	GL-133362
Guideline Name	Non-formulary Descovy and Truvada

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/21/2020
P&T Revision Date:	11/18/2021 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: Descovy (emtricitabine/tenofovir alafenamide)
<p>Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents, for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kg. Indicated in combination with other antiretroviral agents other than protease inhibitors that require a CYP3A inhibitor for the treatment of HIV-1 infection in pediatric patients weighing at least 14 kg and less than 35 kg.</p> <p>HIV-1 Pre-exposure Prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of human immunodeficiency virus-1 (HIV-1) infection from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating Descovy for HIV-1 PrEP. Limitations of Use: The indication does not include use of Descovy in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.</p>
Drug Name: Truvada (emtricitabine/tenofovir disoproxil fumarate)
<p>Treatment of HIV-1 Infection Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.</p>

HIV-1 Pre-Exposure Prophylaxis (PrEP) Indicated in at-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection. Individuals must have a negative HIV-1 test immediately prior to initiating Truvada for HIV-1 PrEP. The dosage of TRUVADA for HIV-1 PrEP is one tablet (containing 200 mg of FTC and 300 mg of TDF) once daily.

2 . Criteria

Product Name: Descovy	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Currently used for the treatment of HIV infection</p>	

Product Name: Brand Truvada	
Diagnosis	Treatment of HIV Infection
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Using for the treatment of HIV infection</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Paid claims or submission of medical records (e.g., chart notes) confirming trial of or intolerance to generic emtricitabine/tenofovir disoproxil fumarate (generic Truvada)</p>	

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: Descovy 200/25 mg*, Brand Truvada 200/300 mg*	
Diagnosis	HIV Pre-exposure Prophylaxis (PrEP)
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Currently used for HIV Pre-exposure Prophylaxis (PrEP)</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes) confirming patient has a history of intolerance or contraindication to generic Truvada 200/300 mg (emtricitabine/tenofovir disoproxil fumarate)</p>	
Notes	Note: *If patient meets criteria above, please approve at GPI-14.

3 . References

1. Descovy Prescribing Information. Gilead Sciences, Inc. Foster City, CA. January 2022.
2. Truvada Prescribing Information. Gilead Sciences, Inc. Foster City, CA. June 2020.

4 . Revision History

Date	Notes
11/1/2023	Annual review: Added Descovy 200/25 mg strength, GPI clean-up, and specified only 200/25 mg strength indicated for PrEP. Added operational note.

Non-steroidal Anti-Inflammatory Agents - PA, ST



Prior Authorization Guideline

Guideline ID	GL-137084
Guideline Name	Non-steroidal Anti-Inflammatory Agents - PA, ST

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/18/2008
P&T Revision Date:	11/16/2019 ; 04/15/2020 ; 04/15/2020 ; 04/15/2020 ; 11/12/2020 ; 04/21/2021 ; 01/19/2022 ; 04/20/2022 ; 07/20/2022 ; 08/18/2022 ; 10/19/2022 ; 01/18/2023 ; 04/19/2023 ; 11/17/2023 ; 04/19/2023 ; 4/19/2023

1 . Indications

Drug Name: Cambia (diclofenac) powder
Migraine Indicated for the acute treatment of migraine attacks with or without aura in adults (18 years of age or older). Limitations of use: Cambia is not indicated for the prophylactic therapy of migraine. The safety and effectiveness of Cambia have not been established for cluster headache, which is present in an older, predominantly male population.
Drug Name: Celebrex (celecoxib)
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older 4) Ankylosing Spondylitis (AS) 5) Acute Pain 6) Primary Dysmenorrhea
Drug Name: Sprix (ketorolac tromethamine) nasal spray
Moderate to moderately severe pain Indicated in adult patients for the short term (up to 5 days) management of moderate to moderately severe pain that requires analgesia at the

opioid level. Limitations of Use: Sprix is not for use in pediatric patients less than 2 years of age.
Drug Name: Tivorbex (indomethacin) capsules
Mild to moderate pain Indicated for treatment of mild to moderate acute pain in adults.
Drug Name: Pennsaid (diclofenac sodium) topical solution
Osteoarthritis (OA) Indicated for the treatment of signs and symptoms of osteoarthritis of the knee(s).
Drug Name: Indocin
Multiple Indications Indicated for the treatment for the following: moderate to severe rheumatoid arthritis including acute flare of chronic disease, moderate to severe ankylosing spondylitis, moderate to severe osteoarthritis, acute painful shoulder (bursitis and/or tendinitis) or acute gouty arthritis.
Drug Name: Vivlodex
Osteoarthritis (OA) Indicated for the treatment of osteoarthritis (OA) pain.
Drug Name: Zorvolex (diclofenac)
Pain Indicated for the treatment of mild to moderate acute pain and management of osteoarthritis (OA) pain.
Drug Name: Lofena
Primary dysmenorrhea, mild to moderate pain, osteoarthritis, and rheumatoid arthritis Indicated for treatment of primary dysmenorrhea, for relief of mild to moderate pain, for relief of the signs and symptoms of osteoarthritis, for the relief of the signs and symptoms of rheumatoid arthritis.
Drug Name: Meloxicam oral suspension 7.5mg/5mL
Multiple Indicated for: 1) Osteoarthritis (OA) 2) Rheumatoid Arthritis (RA) 3) Juvenile Rheumatoid Arthritis (JRA) in patients 2 years of age or older
Drug Name: Zipsor (diclofenac potassium)
Mild to moderate acute pain Indicated for relief of mild to moderate acute pain in adult and pediatric patients 12 years of age and older.

2 . Criteria

Product Name: Sprix nasal spray, Brand Ketorolac nasal spray	
Approval Length	5 Days [A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of moderate to moderately severe pain</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p style="padding-left: 20px;">2.1 Trial and failure, contraindication, or intolerance to oral ketorolac* tablets</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 Patient is unable to take medications orally</p>	
Notes	*Ketorolac is recommended only for patients less than 65 years old. [B, C]

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of osteoarthritis of the knee(s)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p>	

2.1 Trial and failure, contraindication, or intolerance to at least two prescription strength oral NSAIDs (e.g., diclofenac, diclofenac ER, ibuprofen, indomethacin, etc.)

OR

2.2 Documented swallowing disorder

OR

2.3 History of peptic ulcer disease/gastrointestinal bleed

OR

2.4 Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g., use of anticoagulants, chronic corticosteroids)

AND

3 - Trial and failure, contraindication, or intolerance to both of the following: (applies to Brand Pennsaid only)

- generic topical diclofenac 1.5% solution
- generic topical diclofenac 2% solution

Product Name: Brand Pennsaid topical solution, Generic diclofenac topical solution	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response (e.g., improvement in pain symptoms of osteoarthritis) to therapy</p>	

Product Name: Tivorbex*, Brand Diclofenac 50mg, Brand Indomethacin 20mg, Cambia**^, Brand Celebrex, Indocin, Lofena, Vivlodex, Zorvolex, Brand diclofenac 35mg capsule, Meloxicam oral suspension 7.5mg/5mL, Brand Zipsor, generic diclofenac 25mg capsule	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Trial and failure (of a minimum 30 day supply), contraindication, or intolerance to two of the following:</p> <ul style="list-style-type: none"> • diclofenac potassium tab or diclofenac sodium • diflunisal • etodolac • fenoprofen • flurbiprofen • ibuprofen • indomethacin • ketoprofen • ketorolac • meclofenamate • meloxicam • nabumetone • naproxen • oxaprozin • piroxicam • sulindac • tolmetin • celecoxib 	
Notes	<p>*Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including indomethacin, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B] **Per the American Geriatrics Society 2012 updated Beers criteria, chronic use of NSAIDs, including diclofenac, is not recommended for patients greater than or equal to 65 years old unless other alternatives are not effective and patient can take gastroprotective agent (proton pump inhibitor or misoprostol) [B]</p> <p>^Product may be excluded depending on the plan.</p>

3 . Endnotes

- A. The total duration of use of Sprix alone or sequentially with other formulations of ketorolac (IM/IV or oral) must not exceed 5 days because of the potential for increasing the frequency and severity of adverse reactions associated with the recommended doses. Treat patients for the shortest duration possible, and do not exceed 5 days of therapy with Sprix. [1]
- B. This drug is included on the 2012 Beers Criteria for Potentially Inappropriate Medication Use in Older Adults greater than or equal to 65 years old. [3]
- C. This drug is included on the 2013 Health Plan Employer Data and Information Set (HEDIS) list of high-risk medications in the elderly (greater than or equal to 65 years old) [4]

4 . References

1. Sprix prescribing information. Zyla Life Sciences US Inc. Wayne, PA. March 2022.
2. Pennsaid prescribing information. Horizon Therapeutics USA, Inc. Lake Forest, IL. February 2022.
3. The American Geriatrics Society 2012 Beers Criteria Update Expert Panel. American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2012 Apr;60(4):616-31.
4. The National Committee for Quality Assurance (NCQA). Use of high-risk medications in the elderly (DAE). Available at www.ncqa.org. Accessed March 9, 2022.
5. Tivorbex prescribing information. Iroko Pharmaceuticals LLC, Philadelphia, PA. January 2020.
6. Cambia prescribing information. Depomed, Inc, Newark, CA. October 2019.
7. Vivlodex prescribing information. Egalet US Inc. Wayne PA. April 2021.
8. Indocin prescribing information. Iroko Pharmaceuticals, LLC. Philadelphia, PA. October 2018.
9. Zorvolex prescribing information. Zyla Life Sciences US Inc. Wayne, PA. April 2021.
10. Lofena Prescribing Information. Carwin Pharmaceutical Associates, LLC. Hazlet, NJ. July 2021.
11. Diclofenac Sodium Solution Prescribing Information. Apotex Corporation. Weston, FL. April 2022.
12. Meloxicam Oral Suspension Prescribing Information. Avondale Pharmaceuticals, LLC. Birmingham, AL. June 2022.

5 . Revision History

Date	Notes
11/29/2023	Updated GL-135732 to add OptumRx-EHB formulary which was inadvertently removed during reauth verbiage update

Omega-3-Acid Derivatives



Prior Authorization Guideline

Guideline ID	GL-135482
Guideline Name	Omega-3-Acid Derivatives

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/18/2019
P&T Revision Date:	01/15/2020 ; 03/18/2020 ; 09/16/2020 ; 12/16/2020 ; 09/15/2021 ; 11/18/2021 ; 09/21/2022 ; 10/19/2022 ; 09/20/2023 ; 9/20/2023

1 . Indications

Drug Name: Vascepa (icosapent ethyl)
<p>Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.</p> <p>Prevention of Cardiovascular Events Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and 1) established cardiovascular disease or 2) diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.</p>
Drug Name: Generic icosapent ethyl
<p>Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg/dL) hypertriglyceridemia. Limitations of Use: The effect of Vascepa on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.</p>

Prevention of Cardiovascular Events [off-label] Indicated as an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (greater than or equal to 150 mg/dL) and 1) established cardiovascular disease or 2) diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.

Drug Name: Lovaza (omega-3-acid ethyl esters)

Severe Hypertriglyceridemia Indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (greater than or equal to 500 mg per dL) hypertriglyceridemia (HTG). Limitations of Use: The effect of Lovaza on the risk for pancreatitis has not been determined. The effect of Lovaza on cardiovascular mortality and morbidity has not been determined.

2 . Criteria

Product Name: Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypertriglyceridemia</p> <p style="text-align: center;">AND</p> <p>2 - Patient has a pre-treatment triglyceride level greater than or equal to 500 mg/dL</p> <p style="text-align: center;">AND</p> <p>3 - Applies to Brand Lovaza ONLY: Trial and failure, contraindication or intolerance to generic omega-3-acid ethyl esters</p>	

Product Name: Brand Lovaza, Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Severe Hypertriglyceridemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy.</p>	

Product Name: Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Both of the following:</p> <p>1.1 Diagnosis of hypertriglyceridemia</p> <p style="text-align: center;">AND</p> <p>1.2 Patient has a pre-treatment triglyceride level of 150 mg/dL to 499 mg/dL [2,3]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient has established cardiovascular disease (CVD) (e.g., coronary artery disease, cerebrovascular or carotid disease, peripheral artery disease, etc.) [2]</p>	

OR
2.2 Both of the following:
2.2.1 Diagnosis of diabetes mellitus [2]
AND
2.2.2 Patient has two or more risk factors for developing cardiovascular disease (see background section for definitions) [2, 4]
AND
3 - Medication will be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]

Product Name: Brand Vascepa, Generic icosapent ethyl	
Diagnosis	Prevention of Cardiovascular Events
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy.</p> <p style="text-align: center;">AND</p> <p>2 - Medication continues to be used as an adjunct to maximally tolerated statin therapy, unless there is a contraindication or intolerance to statin therapy [2]</p>	

3 . Background

Benefit/Coverage/Program Information

REDUCE-IT Trial Inclusion Criteria for Secondary Prevention Risk Category (Established Cardiovascular Disease) [4]

Man or woman greater than or equal to 45 years of age with one or more of the following:

1. Documented **coronary artery disease** (CAD):

- Documented multi vessel CAD (greater than or equal to 50% stenosis in at least two major epicardial coronary arteries – with or without antecedent revascularization);
- Documented prior MI; or
- Hospitalization for high-risk non-ST-segment elevation acute coronary syndrome (NSTEMI/ACS) (with objective evidence of ischemia: ST-segment deviation or biomarker positivity).

2. Documented **cerebrovascular or carotid disease**:

- Documented prior ischemic stroke;
- Symptomatic carotid artery disease with greater than or equal to 50% carotid arterial stenosis;
- Asymptomatic carotid artery disease with greater than or equal to 70% carotid arterial stenosis per angiography or duplex ultrasound; or
- History of carotid revascularization (catheter-based or surgical).

3. Documented **peripheral arterial disease** (PAD):

- Ankle-brachial index (ABI) less than 0.9 with symptoms of intermittent claudication; or
- History of aorto-iliac or peripheral arterial intervention (catheter-based or surgical).

REDUCE-IT Trial definition of risk factors for cardiovascular disease

- Men greater than or equal to 55 years and women greater than or equal to 65 years
- Cigarette smoker or stopped smoking within the past 3 months
- Hypertension (pretreatment blood pressure greater than or equal to 140 mmHg systolic or greater than or equal to 90 mmHg diastolic)
- HDL-C less than or equal to 40 mg/dL for men or less than or equal to 50 mg/dL for women
- High-sensitivity C-reactive protein greater than 3.0 mg/L
- Creatinine clearance greater than 30 and less than 60 mL/min
- Retinopathy
- Micro- or macro-albuminuria

Definition of maximally tolerated statin therapy

- HIGH-INTENSITY statin therapy (i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg) or is unable to tolerate

OR

- If unable to tolerate HIGH-INTENSITY statin, then MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] or unable to tolerate

OR

- If unable to tolerate MODERATE-INTENSITY statin, then LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg]

OR

- Unable to tolerate low- or moderate-, and high-intensity statins because of contraindications; intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: Myalgia (muscle symptoms without CK elevations) or Myositis (muscle symptoms with CK elevations less than 10 times ULN); or rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [A, 3]

4 . Endnotes

- A. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [3]

5 . References

1. Lovaza prescribing information. GlaxoSmithKline. Research Triangle Park, NC. February 2021.
2. Vascepa prescribing information. Amarin Pharma Inc. Bedminster, NJ. April 2023.
3. Icosapent ethyl prescribing information. Teva Pharmaceuticals. Parsippany, NJ. August 2021.
4. Grundy SM, Stone NJ, Bailey AL, et al. 2018
AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.

5. Supplement to: Bhatt DL, Steg PG, Miller M, et al. Cardiovascular risk reduction with icosapent ethyl for hypertriglyceridemia. N Engl J Med 2019;380:11-22. DOI: 10.1056/NEJMoa1812792

6 . Revision History

Date	Notes
10/26/2023	Program update to standard reauthorization language. No changes to clinical intent.

Oncology Admin - Optum Specialty Fusion & Cancer Guidance Program (MBM)



Prior Authorization Guideline

Guideline ID	GL-118040
Guideline Name	Oncology Admin - Optum Specialty Fusion & Cancer Guidance Program (MBM)

Guideline Note:

Effective Date:	3/1/2023
P&T Approval Date:	1/20/2021
P&T Revision Date:	01/19/2022 ; 07/20/2022 ; 1/18/2023

Note:

This guideline should be used for clients who have elected to participate in the Optum Specialty Fusion program or Medical Benefit Management (MBM) Cancer Guidance Program to review in scope drugs when used for cancer indications.

1 . Criteria

Product Name: In Scope Drug	
Diagnosis	Cancer Indications
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria	

1 - The drug is being used as indicated by National Comprehensive Cancer Network (NCCN) guidelines with a Category of Evidence and Consensus of 1, 2A, or 2B

2 . Revision History

Date	Notes
1/4/2023	Annual review: No updates required.

Ophthalmic Antihistamines

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Prior Authorization Guideline

Guideline ID	GL-135440
Guideline Name	Ophthalmic Antihistamines

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/16/2010
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: LASTACAFT (alcaftadine)	
Allergic Conjunctivitis	Indicated for the prevention of itching associated with allergic conjunctivitis.
Drug Name: ZERVIAE (cetirizine)	
Allergic Conjunctivitis	Indicated for the treatment of ocular itching associated with allergic conjunctivitis.

2 . Criteria

Product Name: Lastacaft, Zerviate	
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, contraindication, or intolerance to both of the following generics or preferred brands:

- azelastine
- olopatadine

3 . References

1. Lastacaft Prescribing Information. Allergan, Inc, Irvine, CA. June 2020.
2. Zerviate Prescribing Information. Eyevance Pharmaceuticals, Lakewood, NJ. October 2023.

4 . Revision History

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

Ophthalmic NSAIDs

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Prior Authorization Guideline

Guideline ID	GL-135439
Guideline Name	Ophthalmic NSAIDs

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/16/2010
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 11/16/2023

1 . Indications

Drug Name: BROMSITE (bromfenac)
Postoperative Inflammation and Prevention of Ocular Pain Indicated for the treatment of postoperative inflammation and prevention of ocular pain in patients undergoing cataract surgery.
Drug Name: ILEVRO (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.
Drug Name: NEVANAC (nepafenac)
Postoperative inflammation Indicated for the treatment of pain and inflammation associated with cataract surgery.

2 . Criteria

Product Name: Ilevro, Nevanac	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Patient is greater than 10 but less than 18 years of age [A]</p> <p style="text-align: center;">OR</p> <p> 2.2 Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to BOTH of the following:</p> <p> 2.2.1 One of the following generics:</p> <ul style="list-style-type: none"> • Diclofenac ophthalmic solution • Flurbiprofen ophthalmic solution • Ketorolac ophthalmic solution <p style="text-align: center;">AND</p> <p> 2.2.2 Prolensa</p>	

Product Name: Bromsite	
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), contraindication, or intolerance to BOTH of the following:

2.1 One of the following generics:

- Diclofenac ophthalmic solution
- Flurbiprofen ophthalmic solution
- Ketorolac ophthalmic solution

AND

2.2 Prolensa

3 . Endnotes

- A. Pediatric patients age greater than 10 but less than 18 years of age are allowed to bypass the trial and failure requirement because Ilevro and Nevanac are approved for this pediatric population, but not Bromsite. The safety and efficacy in pediatric patients below the age of 18 years have not been established for Bromsite. [1, 2, 3]

4 . References

1. Bromsite Prescribing Information. Sun Pharmaceutical Industries, Inc.; Cranbury, NJ. April 2023.
2. Ilevro Prescribing Information. Alcon Laboratories, Inc.; Fort Worth, TX. April 2023.
3. Nevanac Prescribing Information. Alcon Laboratories, Inc.; Fort Worth, TX. April 2023.

5 . Revision History

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

Opioid Quantity Limit Overrides

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Prior Authorization Guideline

Guideline ID	GL-135216
Guideline Name	Opioid Quantity Limit Overrides

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/16/2010
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 10/19/2022 ; 10/18/2023

Note:

Note: The Opioid Quantity Limit Override Administrative Guideline should be used for single opioids that do not have an FDA-maximum dose. For opioids with an FDA-maximum dose, such as APAP-containing opioid products, please refer to the standard Quantity Limit Override Administrative Guideline or the drug-specific guideline, if applicable.

1 . Criteria

Diagnosis	For Malignant Cancer Pain
Approval Length	5 year(s)
Guideline Type	Administrative
Approval Criteria	

<p>1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:</p> <p>1.1 Diagnosis of malignant (cancer) pain*</p>	
Notes	<p>Authorization will be issued for long-term therapy.</p> <p>*For oral fentanyl products, please refer to the drug-specific quantity limit override criteria in the “Oral Fentanyl Products” guideline.</p>

Diagnosis	For Non-Malignant Pain
Approval Length	1 year(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - In the absence of an opioid-specific quantity limit override guideline, the following approval criteria will be used:</p> <p>1.1 Prescribed by a pain specialist or by pain management consultation</p> <p style="text-align: center;">AND</p> <p>1.2 The prescriber maintains and provides chart documentation of the patient’s evaluation, including all of the following:</p> <ul style="list-style-type: none"> • An appropriate patient medical history and physical examination • A description of the nature and intensity of the pain • Documentation of appropriate dose escalation • Documentation of ongoing, periodic review of the course of opioid therapy • An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function) • Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian 	

2 . Revision History

Date	Notes
10/19/2023	Annual review

Opioid Risk Management

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Prior Authorization Guideline

Guideline ID	GL-137342
Guideline Name	Opioid Risk Management

Guideline Note:

Effective Date:	12/5/2023
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1 . Criteria

Product Name: Short-Acting Opioids	
Diagnosis	Cancer or end-of-life care
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Diagnosis of cancer or end of life care</p>	
Notes	Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids

Diagnosis	Postoperative Pain Management
Approval Length	14 Day(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Medication is being used to treat postoperative pain</p> <p style="text-align: center;">AND</p> <p>2 - Medication is not being prescribed for pain related to a dental procedure</p> <p style="text-align: center;">AND</p> <p>3 - The dose being prescribed is the dose that the patient was stable on prior to discharge</p>	
Notes	*Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction.

Product Name: Short-Acting Opioids	
Diagnosis	All Other Diagnoses
Approval Length	6 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Prescriber certifies that there is an active treatment plan that includes but is not limited to a specific treatment objective and the use of other pharmacological and non-pharmacological agents for pain relief as appropriate</p> <p style="text-align: center;">AND</p>	

2 - Prescriber certifies that there has been an informed consent document signed and an addiction risk assessment has been performed

AND

3 - Prescriber certifies that a written/signed agreement between prescriber and patient addressing issues of prescription management, diversion, and the use of other substances exists

Notes

Note: Patients with a cancer drug in their prescription claims history within the previous 365 days will not be subject to a max daily dose, day supply, or fill restriction. Additionally, if criteria is approved patients will not be subject to a max daily dose, day supply, or fill restriction. If the prescriber is unable to certify written documentation to meet criterion (2) and/or (3), written or verbal attestation from the provider may be accepted confirming that the prescriber (or prescriber's representative) has verbally addressed criterion (2) and/or (3) with the patient.

Product Name: Opioid Cough Medications	
Approval Length	6 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older</p>	

Product Name: Opioid Cough Medications*	
Diagnosis	Greater than the maximum dose as specified in the product prescribing information OR compendia for off-label uses (in the absence of a drug-specific guideline)*
Approval Length	60 Day(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - One of the following:</p>	

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition

OR

2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition

AND

3 - One of the following:**

3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information

OR

3.2 Higher dose or quantity is supported by one of following compendia:

- American Hospital Formulary Service Drug Information
- Micromedex DRUGDEX System

Notes

*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acet

	aminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.
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Product Name: Long Acting Opioids: Nucynta ER	
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Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization

<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of cancer</p> <p style="text-align: center;">OR</p> <p>1.2 Patient is receiving opioids as part of end-of-life care</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication or intolerance to at least two of the following preferred products</p> <ul style="list-style-type: none"> • Hydromorphone ER • Morphine sulfate ER • Oxymorphone ER • Hysingla ER • Oxycontin • Xtampza ER 	
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Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 All of the following:</p> <p>1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic</p> <p style="text-align: center;">AND</p> <p>1.1.2 One of the following:</p> <p>1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]</p> <p style="text-align: center;">OR</p> <p>1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy</p> <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia</p> <p style="text-align: center;">AND</p> <p>1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8</p>	

weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

AND

3 - Trial and failure, contraindication or intolerance to at least two of the following preferred products

- Hydromorphone ER

<ul style="list-style-type: none"> • Morphine sulfate ER • Oxymorphone ER • Hysingla ER • Oxycontin • Xtampza ER 	
Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Long Acting Opioids: Nucynta ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation has been provided addressing ALL of the following</p> <ul style="list-style-type: none"> • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g., Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g., DAST-10) • Rationale for not tapering and discontinuing • Patient has been screened for comorbid mental health • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose 	
Notes	If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the request

	ed drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER

Diagnosis	Non-Cancer/End of Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Patient has moderate to severe chronic pain that is non-neuropathic

AND

1.1.2 One of the following:

1.1.2.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.1.2.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

OR

1.2 All of the following:

1.2.1 Patient has moderate to severe neuropathic pain or fibromyalgia

AND

1.2.2 Unless contraindicated, the patient has not exhibited an adequate response to 8 weeks of treatment with gabapentin titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.3 Unless contraindicated, the patient has not exhibited an adequate response to at least 6-8 weeks of treatment with a tricyclic antidepressant (e.g., amitriptyline, nortriptyline, imipramine) titrated to a therapeutic dose (Document drug(s), dose, duration and date of trial)

AND

1.2.4 One of the following:

1.2.4.1 For patients that are filling the prescribed medication for the first time, prior to the start of therapy with the prescribed medication, the patient has failed an adequate (minimum 4 week) trial of a short-acting opioid [Document drug(s), dose, duration and date of trial]

OR

1.2.4.2 Patient is established on the prescribed medication and this prescription is for continuation of therapy

AND

2 - None of the following:

- For use as an as-needed PRN analgesic
- For pain that is mild or not expected to persist for an extended period of time
- For acute pain
- For postoperative pain, unless the patient is already receiving chronic opioid therapy prior to surgery, or if postoperative pain is expected to be moderate to severe and persist for an extended period of time

Notes	If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER	
Diagnosis	Non-Cancer/End-of-Life Care Diagnosis
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation has been provided addressing ALL of the following:</p> <ul style="list-style-type: none"> • Treatment goals are defined, including estimated duration of treatment • Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention • Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory) • Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10) • Rationale for not tapering and discontinuing opioid • Patient has been screened for comorbid mental health conditions • If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP • If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression • Total daily morphine equivalent dose 	
Notes	If the member does not meet the medical necessity reauthorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/stren

	gth combination up to the requested quantity and/or MME for transition to an alternative treatment.
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Product Name: Long Acting Opioids: generic transdermal fentanyl patches, generic methadone 5 mg tablets, generic methadone 10 mg tablets, brand MS CONTIN, generic morphine sulfate ER, generic oxymorphone ER, Brand HYSINGLA ER, OXYCONTIN, generic oxycodone ER, Xtampza ER, generic hydrocodone ER, Generic Morphine Sulfate ER, generic hydromorphone ER	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p> 1.1 Diagnosis of cancer</p> <p style="text-align: center;">OR</p> <p> 1.2 Patient is receiving opioids as part of end-of-life care</p>	

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Cancer or End-of-Life Care
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is being treated for cancer related pain or pain associated with end-of-life</p>	
Notes	*Prior authorization may not apply depending on the plan

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
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Diagnosis	Non- Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - The patient is being treated for pain severe enough to require daily, around-the-clock, longer-term opioid treatment</p> <p style="text-align: center;">AND</p> <p>2 - None of the following:</p> <ul style="list-style-type: none"> • For use as an as-needed PRN analgesic • For pain that is mild or not expected to persist for an extended period of time • For acute pain • For opioid dependence <p style="text-align: center;">AND</p> <p>3 - The patient is not receiving other long-acting opioids concurrently</p>	
Notes	*Prior authorization may not apply depending on the plan. If the member is currently taking the requested long-acting opioid OR was recently switched from another long-acting opioid and does not meet the medical necessity initial authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

Product Name: Brand Butrans, generic buprenorphine patch, Brand Belbuca*, Generic buprenorphine buccal	
Diagnosis	Non-Cancer Pain
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Documentation has been provided addressing ALL of the following

- Treatment goals are defined, including estimated duration of treatment
- Treatment plan includes the use of a nonopioid analgesic and/or nonpharmacologic intervention
- Patient demonstrates meaningful improvement in pain and function using a validated instrument (e.g. Brief Pain Inventory)
- Patient has been screened for substance abuse/opioid dependence using a validated instrument (e.g. DAST-10)
- Rationale for not tapering and discontinuing opioid
- Patient has been screened for comorbid mental health conditions
- If a state prescription drug monitoring program (PDMP) is available, the prescriber has identified there are no concurrently prescribed controlled substances from PDMP
- If used in patients with medical comorbidities or if used concurrently with a benzodiazepine or other drugs that could potentially cause drug-drug interactions, the prescriber has acknowledged that they have completed an assessment of increased risk for respiratory depression
- Total daily morphine equivalent dose

Notes

*Prior authorization may not apply depending on the plan. If the member does not meet the medical necessity reauthorization authorization criteria requirements, a denial should be issued and a maximum 30-day authorization may be authorized one time for the requested drug/strength combination up to the requested quantity and/or MME for transition to an alternative treatment.

2 . References

1. Zohydro ER Prescribing Information. Currax Pharmaceuticals LLC. October 2019.

3 . Revision History

Date	Notes
12/5/2023	update guideline

Oral Fentanyl Products



Prior Authorization Guideline

Guideline ID	GL-129733
Guideline Name	Oral Fentanyl Products

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	11/16/2001
P&T Revision Date:	08/15/2019 ; 09/16/2020 ; 09/15/2021 ; 08/18/2022 ; 8/17/2023

1 . Indications

Drug Name: Abstral (fentanyl)
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, or at least 25 mcg of transdermal fentanyl/hour, or at least 30 mg of oral oxycodone daily, or at least 8 mg of oral hydromorphone daily or at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid medication daily for a week or longer. Patients must remain on around-the-clock opioids when taking Abstral. Limitations of Use: As a part of the TIRF REMS Access program, Abstral may be dispensed only to outpatients enrolled in the program. For inpatient administration of Abstral (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.
Drug Name: Actiq (fentanyl citrate) oral transmucosal lozenge
Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 16 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral

morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Actiq. This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Actiq is contraindicated in the management of acute or postoperative pain. Actiq is intended to be used only in the care of opioid-tolerant cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Actiq Q may be dispensed only to outpatients enrolled in the program. For inpatient administration of Actiq (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Fentora (fentanyl buccal tablet)

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg/hr of transdermal fentanyl, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily, at least 25 mg oral oxymorphone daily, or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids while taking Fentora. This product must not be used in opioid non-tolerant patients because life-threatening hypoventilation and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Fentora is contraindicated in the management of acute or postoperative pain. Fentora is intended to be used only in the care of opioid tolerant cancer patients and only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Fentora may be dispensed only to outpatients enrolled in the program. For inpatient administration of Fentora (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use), patient and prescriber enrollment is not required.

Drug Name: Lazanda (fentanyl) nasal spray

Breakthrough pain Indicated for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking at least: 60 mg of oral morphine/day, 25 mcg of transdermal fentanyl/hour, 30 mg oral oxycodone/day, 8 mg oral hydromorphone/day, 25 mg oral oxymorphone/day, or an equianalgesic dose of another opioid for a week or longer. Patients must remain on around-the-clock opioids when taking Lazanda. Lazanda is contraindicated for patients who are not already tolerant to opioids because life-threatening respiratory depression and death could occur in patients not taking chronic opioids. For this reason, Lazanda is contraindicated in the management of acute or postoperative pain, including headache/migraine, or dental pain. Lazanda is intended to be prescribed only by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use: As a part of the TIRF REMS Access program, Lazanda may be dispensed only to outpatients enrolled in the program. For inpatient administration of Lazanda (e.g., hospitals,

hospices, and long-term care facilities that prescribe for inpatient use), patient enrollment is not required.

Drug Name: Subsys (fentanyl sublingual spray)

Breakthrough pain Indicated for the management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain. Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine daily, at least 25 mcg of transdermal fentanyl/hour, at least 30 mg of oral oxycodone daily, at least 8 mg of oral hydromorphone daily or an equianalgesic dose of another opioid daily for a week or longer. Patients must remain on around-the-clock opioids when taking Subsys . This product must not be used in opioid non-tolerant patients because life-threatening respiratory depression and death could occur at any dose in patients not on a chronic regimen of opioids. For this reason, Subsys is contraindicated in the management of acute or postoperative pain. Subsys is intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain. Limitations of Use As part of the Transmucosal Immediate-Release Fentanyl (TIRF) REMS ACCESS Program, Subsys may be dispensed only to outpatients enrolled in the program. For inpatient administration (e.g., hospitals, hospices, and long-term care facilities that prescribe for inpatient use) of Subsys, patient enrollment is not required.

2 . Criteria

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Lazanda*, or Subsys	
Approval Length	12
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - For the management of breakthrough cancer pain [A]</p> <p style="text-align: center;">AND</p> <p>2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]</p> <ul style="list-style-type: none"> • Morphine sulfate at doses of greater than or equal to 60 mg/day • Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr 	

- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - History of failure or intolerance to generic fentanyl lozenge

AND

4 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Notes

*Product may be excluded depending on the plan

Product Name: Generic fentanyl lozenge

Approval Length

12

Guideline Type

Prior Authorization

Approval Criteria

1 - For the management of breakthrough cancer pain [A]

AND

2 - Patient must have at least a one week history of one of the following medications to demonstrate tolerance to opioids: [3, 4, B]

- Morphine sulfate at doses of greater than or equal to 60 mg/day
- Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr
- Oxycodone at a dose of greater than or equal to 30 mg/day
- Oral hydromorphone at a dose of greater than or equal to 8 mg/day
- Oral oxymorphone at a dose of greater than or equal to 25 mg/day
- An alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day)

AND

3 - The patient is currently taking a long-acting opioid around the clock for cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

Product Name: Abstral*, Brand Actiq, Fentora*, Generic fentanyl citrate*, Generic fentanyl lozenge, Lazanda*, or Subsys

Approval Length	12
Guideline Type	Quantity Limit

Approval Criteria

1 - For the management of breakthrough cancer pain

AND

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

- Pain specialist
- Oncologist
- Hematologist
- Hospice care specialist
- Palliative care specialist

AND

3 - The prescriber maintains and provides chart documentation of the patient's evaluation, including all of the following: [3]

- An appropriate patient medical history and physical examination
- A description of the nature and intensity of the pain
- Documentation of appropriate dose escalation
- Documentation of ongoing, periodic review of the course of opioid therapy
- An updated, comprehensive treatment plan (the treatment plan should state objectives that will be used to determine treatment success, such as pain relief or improved physical and/or psychosocial function)
- Verification that the risks and benefits of the use of the controlled substance have been discussed with the patient, significant other(s), and/or guardian

Notes

*Product may be excluded depending on the plan.

3 . Endnotes

- A. Abstral, Actiq, Fentora, Lazanda, and Subsys are intended to be used only in the care of cancer patients and only by oncologists and pain specialists who are knowledgeable of and skilled in the use of Schedule II opioids to treat cancer pain [1, 2, 5, 6]
- B. Abstral, Actiq, Fentora, Lazanda, and Subsys are only intended for patients who are opioid tolerant. Patients considered opioid tolerant are those who are taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer. [1, 2, 5, 6]

4 . References

1. Actiq Prescribing Information. Cephalon. North Wales, PA. March 2021.
2. Fentora Prescribing Information. Cephalon. North Wales, PA. March 2021.

3. American Academy of Pain Medicine. The use of opioids for the treatment of chronic pain (2013). Available at: <http://www.painmed.org/files/use-of-opioids-for-the-treatment-of-chronic-pain.pdf>. Accessed August 12, 2020.
4. Abstral Prescribing Information. Sentyln Therapeutics, Inc. Solana Beach, CA. October 2019.
5. Lazanda Prescribing Information. West Therapeutic Development, LLC. March 2021.
6. Subsys Prescribing Information. INSYS Therapeutics, Inc. Chandler, AZ. April 2021.

5 . Revision History

Date	Notes
8/11/2023	Annual review

Overactive Bladder Agents

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Prior Authorization Guideline

Guideline ID	GL-121694
Guideline Name	Overactive Bladder Agents

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	3/20/2019
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 07/21/2021 ; 03/16/2022 ; 08/18/2022 ; 3/15/2023

1 . Indications

Drug Name: Gelnique (oxybutynin chloride)
Overactive Bladder Symptoms Indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

2 . Criteria

Product Name: Gelnique	
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), contraindication, or intolerance to two of the following: [2]

- Myrbetriq tablets
- generic darifenacin ER
- generic oxybutynin immediate-release (IR)/extended-release (ER)
- generic solifenacin
- generic tolterodine IR/ER
- generic trospium IR/ER
- generic fesoterodine ER

3 . References

1. Gelnique prescribing information. Allergan USA, Inc. Madison. NJ. March 2019.
2. American Urological Association. Guideline on Diagnosis and Treatment of Non-Neurogenic Overactive Bladder (OAB) in Adults (2019). [https://www.auanet.org/guidelines/overactive-bladder-\(oab\)-guideline](https://www.auanet.org/guidelines/overactive-bladder-(oab)-guideline). Accessed February 14, 2022.

4 . Revision History

Date	Notes
3/15/2023	Annual review - added FDA approved indication criterion.

Oxandrolone

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Prior Authorization Guideline

Guideline ID	GL-134236
Guideline Name	Oxandrolone

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	9/30/2002
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Oxandrolone
<p>Promote weight gain Indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids</p> <p>Bone pain Indicated for the relief of the bone pain frequently accompanying osteoporosis</p>

2 . Criteria

Product Name: Oxandrolone	
Diagnosis	Weight gain
Approval Length	3 Month [A]

Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used as adjunctive therapy to promote weight gain</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of one of the following:</p> <ul style="list-style-type: none"> • Extensive surgery • Chronic infections • Severe trauma • Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to nutritional supplements</p> <p style="text-align: center;">AND</p> <p>4 - A nutritional consult was performed</p>	

Product Name: Oxandrolone	
Diagnosis	Weight gain
Approval Length	3 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Patient demonstrates a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass

Product Name: Oxandrolone

Diagnosis	Bone pain
Approval Length	1 Month [A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of bone pain associated with osteoporosis

Product Name: Oxandrolone

Diagnosis	Protein catabolism
Approval Length	3 Month [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Used to counter balance protein catabolism associated with chronic corticosteroid administration

Product Name: Oxandrolone

Diagnosis	Protein catabolism
Approval Length	3 Month [A]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates a positive clinical response to therapy as evidenced by an improvement in weight gain or increase in lean body mass

3 . Endnotes

- A. Per oxandrolone prescribing information, a course of therapy of 2 to 4 weeks is usually adequate, and may be repeated intermittently as indicated. [1]

4 . References

1. Oxandrolone Prescribing Information. Upsher-Smith Laboratories, LLC. Maple Grove, MN. July 2020.

5 . Revision History

Date	Notes
10/3/2023	Program update to standard reauthorization language. No changes to clinical intent

PCSK9 Inhibitors - PA, NF



Prior Authorization Guideline

Guideline ID	GL-127628
Guideline Name	PCSK9 Inhibitors - PA, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	5/20/2015
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 03/17/2021 ; 06/16/2021 ; 08/19/2021 ; 11/18/2021 ; 03/16/2022 ; 06/15/2022 ; 03/15/2023 ; 7/19/2023

1 . Indications

Drug Name: Repatha (evolocumab)
<p>Prevention of Cardiovascular Events Indicated in adults with established cardiovascular disease to reduce the risk of myocardial infarction, stroke, and coronary revascularization.</p> <p>Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia) Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.</p> <p>Heterozygous Familial Hypercholesterolemia (HeFH) Indicated as an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with HeFH, to reduce LDL-C</p> <p>Homozygous Familial Hypercholesterolemia Indicated as an adjunct to other LDL-C-lowering therapies in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH), to reduce LDL-C</p>
Drug Name: Praluent (alirocumab)

Prevention of Cardiovascular Events Indicated to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.

Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia) Indicated as an adjunct to diet, alone or in combination with other low density lipoprotein cholesterol (LDL-C)-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.

Homozygous Familial Hypercholesterolemia Indicated as an adjunct to other LDL-C lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Repatha	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]</p> <p>1.1.1.1 Both of the following: [4]</p> <p>1.1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]</p> <p style="text-align: center;">AND</p>	

1.1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.1.2 Both of the following:

1.1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

AND

1.1.2 Patient is 10 years of age or older

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack

- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [F]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-

40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [F]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 15-16]

3.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD

- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following: [F]

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

Product Name: Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 One of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms:

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-

40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [F]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 15-16]

3.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Documentation of one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 55 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

4 - Trial and failure, contraindication, or intolerance to Repatha

Product Name: Repatha, Praluent (F)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose</p> <p style="text-align: center;">OR</p> <p>1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)</p> <p style="text-align: center;">AND</p> <p>2 - Documentation of a reduction in LDL-C levels while on Repatha or Praluent therapy</p>	

Product Name: Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p>	

1 - One of the following diagnoses:

1.1 Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: [1-2, B]

1.1.1 Both of the following: [4]

1.1.1.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.1.2 One of the following: [4]

- Family history of myocardial infarction in first-degree relative less than 60 years of age
- Family history of myocardial infarction in second-degree relative less than 50 years of age
- Family history of LDL-C greater than 190 mg/dL in first- or second-degree relative
- Family history of familial hypercholesterolemia in first- or second-degree relative [21]
- Family history of tendinous xanthomata and/or arcus cornealis in first- or second-degree relative

OR

1.1.2 Both of the following:

1.1.2.1 Untreated/pre-treatment LDL-cholesterol (LDL-C) greater than 190 mg/dL (greater than 155 mg/dL if less than 16 years of age) [4]

AND

1.1.2.2 Submission of medical records (e.g., chart notes, laboratory values) documenting one of the following:

- Functional mutation in the LDL receptor, ApoB, or PCSK9 gene [3-4]
- Tendinous xanthomata [3-4]
- Arcus cornealis before age 45 [3]

OR

1.2 Atherosclerotic cardiovascular disease (ASCVD) as confirmed by one of the following: [1, 2, 5]

- Acute coronary syndromes
- History of myocardial infarction
- Stable or unstable angina
- Coronary or other arterial revascularization
- Stroke
- Transient ischemic attack
- Peripheral arterial disease presumed to be of atherosclerotic origin

OR

1.3 Primary hyperlipidemia

AND

2 - One of the following: [1, 2, 5]

2.1 Patient has been receiving at least 12 consecutive weeks of HIGH-INTENSITY statin therapy [i.e., atorvastatin 40-80 mg, rosuvastatin 20-40 mg] and will continue to receive a HIGH-INTENSITY statin at maximally tolerated dose

OR

2.2 Both of the following:

2.2.1 Patient is unable to tolerate high-intensity statin as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms: [F]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN])

AND

2.2.2 One of the following:

2.2.2.1 Patient has been receiving at least 12 consecutive weeks of MODERATE-INTENSITY statin therapy [i.e., atorvastatin 10-20 mg, rosuvastatin 5-10 mg, simvastatin 20-

40 mg, pravastatin 40-80 mg, lovastatin 40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 40 mg twice daily, or Livalo (pitavastatin) 2-4 mg] and will continue to receive a MODERATE-INTENSITY statin at maximally tolerated dose

OR

2.2.2.2 Patient has been receiving at least 12 consecutive weeks of LOW-INTENSITY statin therapy [i.e., simvastatin 10 mg, pravastatin 10-20 mg, lovastatin 20 mg, fluvastatin 20-40 mg, Livalo (pitavastatin) 1 mg] and will continue to receive a LOW-INTENSITY statin at maximally tolerated dose

OR

2.3 Patient is unable to tolerate low- or moderate-, and high-intensity statins as evidenced by one of the following intolerable and persistent (i.e., more than 2 weeks) symptoms for low- or moderate-, and high-intensity statins: [F]

- Myalgia (muscle symptoms without CK elevations)
- Myositis (muscle symptoms with CK elevations less than 10 times ULN)

OR

2.4 Patient has a labeled contraindication to all statins

OR

2.5 Patient has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN [5]

AND

3 - One of the following: [8-9, 17-18]

3.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid-lowering therapy within the last 120 days:

- LDL-C greater than or equal to 100 mg/dL with ASCVD
- LDL-C greater than or equal to 130 mg/dL without ASCVD

OR

3.2 Both of the following:

3.2.1 Submission of medical records (e.g., laboratory values) documenting one of the following LDL-C values while on maximally tolerated lipid lowering therapy within the last 120 days:

- LDL-C between 70 mg/dL and 99 mg/dL with ASCVD
- LDL-C between 100 mg/dL and 129 mg/dL without ASCVD

AND

3.2.2 One of the following:

3.2.2.1 Patient has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) therapy as adjunct to maximally tolerated statin therapy [A]

OR

3.2.2.2 Patient has a history of contraindication, or intolerance to ezetimibe

OR

3.3 Both of the following:

3.3.1 Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe)

AND

3.3.2 Submission of medical records (e.g., laboratory values) documenting LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits

AND

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

Product Name: Praluent (NF)	
Diagnosis	Primary Hyperlipidemia [Including Heterozygous Familial Hypercholesterolemia (HeFH), Atherosclerotic Cardiovascular Disease (ASCVD), and Secondary Prevention of Cardiovascular Events in Patients with ASCVD]
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p style="padding-left: 20px;">1.1 Patient continues to receive other lipid-lowering therapy (e.g., statins, ezetimibe) at the maximally tolerated dose</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statins, ezetimibe)</p> <p style="text-align: center;">AND</p> <p>2 - Submission of medical records (e.g., chart notes, laboratory values) documenting a reduction in LDL-C levels while on Praluent therapy</p> <p style="text-align: center;">AND</p> <p>3 - Paid claims or submission of medical records (e.g., chart notes) confirming trial and failure, contraindication, or intolerance to Repatha</p>	

Product Name: Repatha

Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]</p> <p>1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 One of the following:</p> <ul style="list-style-type: none"> • Untreated/pre-treatment LDL-C greater than 500 mg/dL • Treated LDL-C greater than 300 mg/dL <p style="text-align: center;">AND</p> <p>1.2.2 One of the following:</p> <ul style="list-style-type: none"> • Xanthoma before 10 years of age • Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p style="text-align: center;">OR</p>	

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

3 - Patient is 10 years of age or older

Product Name: Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]</p> <p>1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 One of the following:</p> <ul style="list-style-type: none"> • Untreated/pre-treatment LDL-C greater than 500 mg/dL • Treated LDL-C greater than 300 mg/dL <p style="text-align: center;">AND</p> <p>1.2.2 One of the following:</p> <ul style="list-style-type: none"> • Xanthoma before 10 years of age 	

<ul style="list-style-type: none"> Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p style="text-align: center;">OR</p> <p>2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to Repatha</p>

Product Name: Repatha, Praluent (F)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p style="text-align: center;">OR</p> <p>1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)</p>	

AND

2 - Documentation of LDL-C reduction while on Repatha or Praluent therapy

Product Name: Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	6 Months [A]
Therapy Stage	Initial Authorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of homozygous familial hypercholesterolemia as confirmed by one of the following: [11-13]</p> <p>1.1 Genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (i.e., LDLRAP1 or ARH)</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <p>1.2.1 One of the following:</p> <ul style="list-style-type: none"> • Untreated/pre-treatment LDL-C greater than 500 mg/dL • Treated LDL-C greater than 300 mg/dL <p style="text-align: center;">AND</p> <p>1.2.2 One of the following:</p> <ul style="list-style-type: none"> • Xanthoma before 10 years of age • Evidence of heterozygous familial hypercholesterolemia (HeFH) in both parents 	

AND

2 - One of the following:

2.1 Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe)

OR

2.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)

AND

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

Product Name: Praluent (NF)	
Diagnosis	Homozygous Familial Hypercholesterolemia
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient continues to receive other lipid-lowering therapy (e.g., statin, ezetimibe)</p> <p style="text-align: center;">OR</p> <p>1.2 Patient has a documented inability to take other lipid-lowering therapy (e.g., statin, ezetimibe)</p>	

AND

2 - Submission of medical records (e.g., chart notes, laboratory values) documenting LDL-C reduction while on Praluent therapy

AND

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

3 . Endnotes

- A. Per the 2018 ACC/AHA national treatment guidelines, adherence, response to therapy, and adverse effects should be monitored within 4 -12 weeks following LDL-C lowering medication initiation or dose adjustment, repeated every 3 to 12 months as needed. [5]
- B. In the Praluent and Repatha pivotal trials that enrolled patients with HeFH, the diagnosis of HeFH was made either by genotyping or clinical criteria ("definite FH" using either the Simon Broome or WHO/Dutch Lipid Network criteria). [1-4]
- C. IMPROVE-IT was a prospective RCT evaluating the addition of ezetimibe to simvastatin 40 mg in a high-risk patient population for secondary prevention over 7 years. The addition of ezetimibe significantly reduced ASCVD events, albeit very modestly (HR 0.936; 95% CI 0.887, 0.988; $p = 0.016$; number needed to treat [NNT] = 50). [6]
- D. Per the 2018 ACC/AHA national treatment guidelines, it is reasonable to use the following as indicators of anticipated therapeutic response to the recommended intensity of statin therapy. Focus is on the intensity of the statin therapy. As an aid to monitoring:
a) High-intensity statin therapy generally results in an average LDL-C reduction of greater than or equal to 50% from the untreated baseline; b) Moderate-intensity statin therapy generally results in an average LDL-C reduction of 30 to 49% from the untreated baseline. [5]
- E. FOURIER, a double blind, placebo controlled, RCT was the first completed cardiovascular outcomes trial for the PCSK9 inhibitors. The trial enrolled 27,564 high-risk patients with cardiovascular disease and LDL-C levels greater than or equal to 70 mg/dL while receiving optimized lipid-lowering therapy (99.7% of patients were receiving moderate- or high-intensity statins). The composite endpoint of CV death, myocardial infarction, stroke, hospitalization for unstable angina, and coronary revascularization occurred in 9.8% of evolocumab-treated patients vs. 11.3% of placebo-treated patients (treatment difference of 1.5%; HR 0.85; 95% CI, 0.79 to 0.92; $p < 0.001$) during a median follow-up period of 26 months. No benefit was identified in CV death or death from any cause. [18]
- F. Use of PCSK9 inhibitors for the primary prevention of cardiovascular events and/or for the lowering of low-density lipoprotein cholesterol (LDL-C) in patients with primary hyperlipidemia who do not have heterozygous familial hypercholesterolemia or

established atherosclerotic cardiovascular disease (ASCVD) is not supported by the 2018 ACC/AHA Cholesterol Clinical Practice Guidelines. Per consult with cardiologist, use of PCSK9 inhibitors for primary prevention should be limited to the FH population. [5, 22]

- G. In patients treated with statins, it is recommended to measure creatine kinase levels in individuals with severe statin-associated muscle symptoms. [5]

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5 . Revision History

Date	Notes
7/6/2023	Update to account for 2022 ACC recommendations of a lower LDL th reshod of 55mg/dl for patients with ASCVD at very high risk.

Prior Authorization Administrative Guideline

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Prior Authorization Guideline

Guideline ID	GL-135958
Guideline Name	Prior Authorization Administrative Guideline

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	2/15/2011
P&T Revision Date:	10/16/2019 ; 10/21/2020 ; 10/20/2021 ; 10/19/2022 ; 11/16/2023

Note:

The purpose of this guideline is to establish policies and procedures on how to handle (1) formulary drugs with a prior authorization requirement that do not have official criteria posted or available, and (2) new FDA-approved indications, which are not addressed in the existing drug-specific prior authorization guideline. This guideline will not apply to drugs that are benefit exclusions, drugs with step therapy edits, drugs that require quantity limit review only, non-formulary drugs, or drugs that are not reviewed for prior authorization by OptumRx.

1 . Criteria

Product Name: Drugs with a prior authorization requirement for which a guideline is unavailable, OR new FDA-approved indications which are not addressed in the existing drug-specific prior authorization guideline	
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

Notes	This guideline should not be used to address step therapy.
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2 . Revision History

Date	Notes
11/3/2023	2023 UM Annual Review.

Proton Pump Inhibitors



Prior Authorization Guideline

Guideline ID	GL-136660
Guideline Name	Proton Pump Inhibitors

Guideline Note:

Effective Date:	12/1/2023
P&T Approval Date:	2/15/2011

1 . Indications

Drug Name: Aciphex (rabeprazole)
<p>Healing of Erosive or Ulcerative GERD in Adults Indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative GERD. For those patients who have not healed after 8 weeks of treatment, an additional 8-week course of Aciphex may be considered.</p> <p>Maintenance of Healing of Erosive or Ulcerative GERD in Adults Indicated for maintaining healing and reduction in relapse rates of heartburn symptoms in patients with erosive or ulcerative gastroesophageal reflux disease (GERD Maintenance). Controlled studies do not extend beyond 12 months.</p> <p>Treatment of Symptomatic Gastroesophageal Reflux Disease (GERD) in Adults Indicated for the treatment of daytime and nighttime heartburn and other symptoms associated with GERD in adults for up to 4 weeks.</p> <p>Healing of Duodenal Ulcers in Adults Indicated for short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers. Most patients heal within 4 weeks.</p> <p>Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults In combination with amoxicillin and clarithromycin as a three drug regimen, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or</p>

history within the past 5 years) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome in Adults

Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Short-term Treatment of Symptomatic GERD in Adolescent Patients 12 years of Age and Older

Indicated for the treatment of symptomatic GERD in adolescents 12 years of age and above for up to 8 weeks.

Drug Name: Aciphex Sprinkle (rabeprazole)

Patients 1 to 11 Years of Age Indicated for treatment of GERD in pediatric patients 1 to 11 years of age for up to 12 weeks.

Drug Name: Dexilant (dexlansoprazole)

Healing of Erosive Esophagitis Indicated in patients 12 years of age and older for healing of all grades of erosive esophagitis for up to 8 weeks.

Maintenance of Healed Erosive Esophagitis Indicated in patients 12 years of age and older to maintain healing of erosive esophagitis and relief of heartburn for up to six months in adults and 16 weeks in patients 12 to 17 years of age.

Symptomatic Non-Erosive GERD Indicated in patients 12 years of age and older for the treatment of heartburn associated with symptomatic non-erosive GERD for 4 weeks.

Drug Name: Esomeprazole strontium

Healing of Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of esomeprazole strontium may be considered.

Maintenance of Healing of Erosive Esophagitis Indicated to maintain symptom resolution and healing of erosive esophagitis. Controlled studies do not extend beyond 6 months.

Symptomatic Gastroesophageal Reflux Disease Indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults.

Risk Reduction of NSAID-Associated Gastric Ulcer in Adults Indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk for developing gastric ulcers. Patients are considered to be at risk either due to their age (greater than or equal to 60) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

***H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence in Adults In**

combination with amoxicillin and clarithromycin, indicated for the treatment of patients with H. pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome in Adults

Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome.

Drug Name: Konvomep (omeprazole and sodium bicarbonate)

Gastric Ulcer Indicated for the short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients Indicated for the reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients.

Drug Name: Nexium (esomeprazole)

Healing of Erosive Esophagitis Nexium delayed-release capsules and Nexium delayed-release oral suspension are indicated for the short-term treatment (4 to 8 weeks) in the healing and symptomatic resolution of diagnostically confirmed erosive esophagitis in adults. For those patients who have not healed after 4 to 8 weeks of treatment, an additional 4 to 8 week course of Nexium may be considered. In pediatric patients 1 month to less than 1 year of age, Nexium delayed-release oral suspension is indicated for short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-mediated GERD. In pediatric patients 1 year to 11 years of age, Nexium delayed-release oral suspension is indicated for the short-term treatment (8 weeks) for the healing of EE. In pediatric patients 12 years to 17 years of age, Nexium delayed-release capsules and Nexium delayed-release oral suspension are indicated for for the short-term treatment (4 to 8 weeks) for the healing of EE.

Maintenance of Healing of Erosive Esophagitis NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the maintenance of healing of erosive esophagitis in adults. Controlled studies do not extend beyond 6 months.

Symptomatic GERD NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for short-term treatment (4 to 8 weeks) of heartburn and other symptoms associated with GERD in adults. NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for short-term treatment (4 weeks) of heartburn and other symptoms associated with GERD in pediatric patients 12 years to 17 years of age. NEXIUM for delayed-release oral suspension is indicated for short-term treatment (up to 8 weeks) of heartburn and other symptoms associated with GERD in pediatric patients 1 year to 11 years of age.

Risk Reduction of NSAID-Associated Gastric Ulcer NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in adult patients at risk for developing gastric ulcers. Patients are considered to be at risk due to their age (60

years and older) and/or documented history of gastric ulcers. Controlled studies do not extend beyond 6 months.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence

Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. Triple therapy: NEXIUM delayed-release capsules or NEXIUM for delayed-release oral suspension in combination with amoxicillin and clarithromycin is indicated for the treatment of adult patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome NEXIUM delayed-release capsules and NEXIUM for delayed-release oral suspension are indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome, in adults.

Drug Name: Prevacid (lansoprazole)

Short-Term Treatment of Active Duodenal Ulcer Indicated for short-term treatment (for 4 weeks) for healing and symptom relief of active duodenal ulcer in adults.

H. pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with amoxicillin plus clarithromycin as triple therapy, indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence. In combination with amoxicillin as dual therapy, indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or one-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence.

Maintenance of Healed Duodenal Ulcers Indicated to maintain healing of duodenal ulcers in adults. Controlled studies do not extend beyond 12 months.

Short-Term Treatment of Active Benign Gastric Ulcer Indicated for short-term treatment (up to 8 weeks) for healing and symptom relief of active benign gastric ulcer in adults.

Healing of NSAID-Associated Gastric Ulcer Indicated in adults for the treatment of NSAID-associated gastric ulcer in patients who continue NSAID use. Controlled studies did not extend beyond 8 weeks.

Risk Reduction of NSAID-Associated Gastric Ulcer Indicated in adults for reducing the risk of NSAID-associated gastric ulcers in patients with a history of a documented gastric ulcer who require the use of an NSAID. Controlled studies did not extend beyond 12 weeks.

Short-Term Treatment of Symptomatic GERD Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for the treatment of heartburn and other symptoms associated with GERD.

Short-Term Treatment of Erosive Esophagitis Indicated for short-term treatment in adults and pediatric patients 12 to 17 years of age (up to eight weeks) and pediatric patients one to 11 years of age (up to 12 weeks) for healing and symptom relief of all grades of erosive esophagitis. For adults who do not heal with Prevacid for 8 weeks (5 to 10%), it may be helpful to give an additional 8 weeks of treatment. If there is a recurrence of erosive esophagitis, an additional 8-week course of Prevacid may be considered.

Maintenance of Healing of Erosive Esophagitis Indicated in adults to maintain healing of EE. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated in adults for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Drug Name: Prilosec (omeprazole)

Treatment of Active Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer in adults. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Helicobacter pylori Eradication to Reduce the Risk of Duodenal Ulcer Recurrence In combination with clarithromycin and amoxicillin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease (active or up to 1-year history) to eradicate H. pylori in adults. In combination with clarithromycin, indicated for treatment of patients with H. pylori infection and duodenal ulcer disease to eradicate H. pylori in adults. Eradication of H. pylori has been shown to reduce the risk of duodenal ulcer recurrence. Among patients who fail therapy, Prilosec with clarithromycin is more likely to be associated with the development of clarithromycin resistance as compared with triple therapy. In patients who fail therapy, susceptibility testing should be done. If resistance to clarithromycin is demonstrated or susceptibility testing is not possible, alternative antimicrobial therapy should be instituted.

Gastric Ulcer (adults) Indicated for short-term treatment (4 to 8 weeks) of active benign gastric ulcer in adults.

Treatment of Symptomatic GERD (adults and pediatric patients) Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks in patients 1 year of age and older.

Erosive Esophagitis Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD that has been diagnosed by endoscopy in patients 1 year of age and older. The efficacy of Prilosec used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of erosive esophagitis or GERD symptoms, additional 4 to 8 week courses of omeprazole may be considered. Also indicated for the short-term treatment (up to 6 weeks) of erosive esophagitis due to acid-mediated GERD in pediatric patients 1 month to less than 1 year of age.

Maintenance of Healing of Erosive Esophagitis Indicated for the maintenance healing of EE due to acid-mediated GERD in patients 1 year of age and older. Controlled studies do not

extend beyond 12 months.

Pathological Hypersecretory Conditions (adults) Indicated for the long-term treatment of pathological hypersecretory conditions (e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas and systemic mastocytosis) in adults.

Drug Name: Protonix (pantoprazole)

Short-Term Treatment of Erosive Esophagitis Associated With GERD Indicated in adults and pediatric patients five years of age and older for the short-term treatment (up to 8 weeks) in the healing and symptomatic relief of erosive esophagitis. For those adult patients who have not healed after 8 weeks of treatment, an additional 8-week course of Protonix may be considered. Safety of treatment beyond 8 weeks in pediatric patients has not been established.

Maintenance of Healing of Erosive Esophagitis Indicated for maintenance of healing of erosive esophagitis and reduction in relapse rates of daytime and nighttime heartburn symptoms in adult patients with GERD. Controlled studies did not extend beyond 12 months.

Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome Indicated for the long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.

Drug Name: Zegerid (omeprazole/sodium bicarbonate)

Duodenal Ulcer Indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

Gastric Ulcer Indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer.

Symptomatic GERD Indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks.

Erosive Esophagitis due to acid-mediated GERD Indicated for the short-term treatment (4 to 8 weeks) of erosive esophagitis due to acid-mediated GERD which has been diagnosed by endoscopy in adults. The efficacy of ZEGERID used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8-week courses of ZEGERID may be considered.

Maintenance of Healing of Erosive Esophagitis Due to Acid-Mediated GERD Indicated to maintain healing of erosive esophagitis due to acid-mediated GERD. Controlled studies do not extend beyond 12 months.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only) Indicated for the reduction of risk of upper GI bleeding in critically ill patients.

2 . Criteria

Product Name: Aciphex Sprinkle, Brand Aciphex tablets, Authorized Brand Alternative Rabeprazole Sprinkle, Brand Dexilant capsules, Esomeprazole strontium capsules, Brand Prevacid capsules, Brand Prevacid Solutab, Prilosec suspension, Brand Protonix tablets, Brand Protonix suspension, Brand Zegerid capsules, Brand Zegerid suspension, First-Lansoprazole suspension, First-Omeprazole suspension, Konvomep suspension, First Pantoprazole	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure or intolerance to at least two of the following:</p> <ul style="list-style-type: none"> • dexlansoprazole • esomeprazole • omeprazole • lansoprazole (capsule) • pantoprazole • rabeprazole (tablets) 	

Product Name: Aciphex Sprinkle*, Brand Aciphex tablets*, Authorized Brand Alternative Rabeprazole Sprinkle*, Generic rabeprazole tablets, Brand Dexilant capsules, Esomeprazole strontium capsules*, Brand Nexium capsules, Generic esomeprazole capsules, Nexium suspension, Brand Prevacid capsules*, Generic lansoprazole capsules, Brand Prevacid Solutab*, Generic lansoprazole orally disintegrating tablets, Generic omeprazole capsules, Prilosec suspension*, Brand Protonix tablets*, Generic pantoprazole tablets, Brand Protonix suspension*, Generic pantoprazole suspension, Brand Zegerid capsules*, Generic omeprazole-sodium bicarbonate capsules, Brand Zegerid suspension*, Generic omeprazole-sodium bicarbonate suspension, Generic dexlansoprazole capsules	
Diagnosis	Twice-daily (BID) PPI Therapy**
Guideline Type	Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Trial and inadequate response to once daily PPI regimen

OR

1.2 A once daily PPI regimen is not appropriate to treat the patient’s condition

AND

2 - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product[^]:

- American Hospital Formulary Service Drug Information
- Micromedex Drug System
- Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal

Notes

Authorization of therapy will be issued for 12 months for all diagnoses, except for H. pylori eradication. For H. pylori eradication, authorization will be issued for 14 days.

*These products may require step therapy.

**Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline.

[^]Support found in labeling or compendia should be evaluated regardless of indication.

3 . Background

Clinical Practice Guidelines

BID Max Range Dosing Table [12-15]

***Intent of table below is to provide a quick reference for BID dosing range listed by requested product. If the requested dose exceeds max dose listed below, PA team members should still review at point of request for clinical appropriateness as off label support continuously evolves. [Last Reviewed: 8/3/22]**

	Aciphex (rabeprazole)	Dexilant (dexlansoprazole)	Esomeprazole strontium	Nexium (esomeprazole)	Prevacid (Lansoprazole)	Prilosec (omeprazole)	Protonix (pantoprazole)	Zegerid (omeprazole/sodium bicarbonate)
DOSE RANGE	20 to 60 mg BID	30 mg BID	49.3 mg BID (Max = 240 mg/day)	20 to 40 mg BID (Max = 240 mg/day)	30 to 90 mg BID	20 to 40mg BID (Max = 360 mg/day ; divide doses above 80mg)	40 to 80 mg BID (Max = 240 mg/day)	No BID support found at time of last annual review

4 . Endnotes

- A. Both strengths of Zegerid capsule and powder for oral suspension have identical sodium bicarbonate content, respectively. Do not substitute two 20 mg capsules/packets for one 40 mg dose [4].

5 . References

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3. Esomeprazole Strontium Prescribing Information. Amneal Pharmaceuticals LLC. Glasgow, KY. January 2021.

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6 . Revision History

Date	Notes
11/21/2023	Corrected effective date to 12/1/2023

Provigil (modafinil), Nuvigil (armodafinil)



Prior Authorization Guideline

Guideline ID	GL-134202
Guideline Name	Provigil (modafinil), Nuvigil (armodafinil)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: Provigil (modafinil)
<p>Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy.</p> <p>Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Provigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating and during treatment with Provigil for excessive sleepiness.</p> <p>Shift work disorder (SWD) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder.</p> <p>Off Label Uses: Fatigue due to multiple sclerosis (MS) In a double-blind, placebo-controlled study, treatment with modafinil significantly improved fatigue symptoms compared with placebo in patients with multiple sclerosis (MS) [5,7]</p> <p>Adjunctive therapy for the treatment of major depressive disorder (MDD) or bipolar</p>

disorder In a meta-analysis of 4 MDD RCTs and 2 bipolar depression RCTs, adjunctive treatment with modafinil improved overall depression scores, remission rates, and fatigue symptoms. [5,9]

Drug Name: Nuvigil (armodafinil)

Narcolepsy Indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy.

Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with obstructive sleep apnea (OSA). Limitations of Use: Nuvigil is indicated to treat excessive sleepiness and not as treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Nuvigil for excessive sleepiness.

Shift work disorder (SWD) Indicated to improve wakefulness in adult patients with excessive sleepiness associated with shift work disorder.

2 . Criteria

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of obstructive sleep apnea defined by one of the following: [1,4,10]</p> <p> 1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [6,10,D, F]</p> <p style="text-align: center;">OR</p> <p> 1.2 Both of the following: [6,10,D, F]</p>	

1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)

AND

1.2.2 One of the following symptoms:

- Unintentional sleep episodes during wakefulness
- Daytime sleepiness
- Unrefreshing sleep
- Fatigue
- Insomnia
- Waking up breath holding, gasping, or choking
- Loud snoring
- Breathing interruptions during sleep

AND

2 - Both of the following:

2.1 Standard treatments for the underlying obstruction (e.g., continuous positive airway pressure [CPAP], bi-level positive airway pressure [BPAP], etc.) have been used for 3 months or longer [5]

AND

2.2 Patient is fully compliant with standard treatment(s) for the underlying obstruction.

AND

3 - Trial and failure or intolerance to modafinil (applies to Provigil only)

AND

4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 Months [G]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient continues to be fully compliant on concurrent standard treatment(s) for the underlying obstruction (e.g., CPAP, BPAP, etc.)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is experiencing relief of symptomatic hypersomnolence with use</p>	

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [G]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Shift Work Disorder confirmed by one of the following: [10,12]</p> <p>1.1 Symptoms of excessive sleepiness or insomnia, for at least 3 months, which is temporally associated with a work period (usually night work) that occurs during the habitual sleep phase</p> <p style="text-align: center;">OR</p> <p>1.2 Sleep study demonstrating loss of a normal sleep wake pattern (i.e., disturbed chronobiologic rhythmicity)</p>	

<p>AND</p> <p>2 - Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia [10,12]</p> <p>AND</p> <p>3 - Trial and failure or intolerance to modafinil (applies to Provigil only)</p> <p>AND</p> <p>4 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)</p>
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Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Shift Work Disorder (SWD)
Approval Length	6 Months [G]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [5,7,E]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

<p>1 - Diagnosis of multiple sclerosis (MS)</p> <p style="text-align: center;">AND</p> <p>2 - Patient is experiencing fatigue</p> <p style="text-align: center;">AND</p> <p>3 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)</p> <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to modafinil (applies to Provigil only)</p>
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Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Fatigue due to MS (off-label) [5,7,E]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is experiencing relief of fatigue with therapy</p> <p style="text-align: center;">AND</p> <p>2 - Used in combination with standard educational therapies (e.g., psychoeducation, behavioral programs, scheduled naps, additional non-pharmacological therapies, etc.)</p>	

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy

Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [1,4,10,A-C]</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure or intolerance to modafinil (applies to Provigil only)</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure or intolerance to armodafinil (applies to Nuvigil only)</p>	

Product Name: Generic armodafinil, Generic modafinil, Brand Nuvigil, or Brand Provigil	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label)[5,9]
Approval Length	6 month(s)
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Treatment-resistant depression, defined as both of the following:</p> <p>1.1 Diagnosis of one of the following [9]:</p> <ul style="list-style-type: none"> • Major depressive disorder (MDD) • Bipolar depression <p style="text-align: center;">AND</p> <p>1.2 History of failure, contraindication, or intolerance to at least two antidepressants from different classes (e.g., SSRIs, SNRIs, bupropion)</p> <p style="text-align: center;">AND</p> <p>2 - Used as adjunctive therapy</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure or intolerance to modafinil (applies to Provigil only)</p>	

Product Name: Generic modafinil, Brand Provigil	
Diagnosis	Adjunctive therapy for the treatment of major depressive disorder or bipolar depression (off-label)[5,9]
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

AND

2 - Used as adjunctive therapy

Product Name: Generic armodafinil 50 mg, Generic modafinil 100 mg, Brand Nuvigil 50 mg, or Brand Provigil 100 mg

Guideline Type

Quantity Limit

Approval Criteria

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication.

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.

AND

2 - One of the following:

2.1 For titration purposes (one time authorization)

OR

2.2 Requested strength/dose is commercially unavailable

OR

2.3 Patient is on a dose alternating schedule

Notes	Authorization will be issued for the length of therapy based on indication, except for titration purposes (Narcolepsy: 12 months, All other indications: 6 months). Not to exceed maximum FDA-approved dose.
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Product Name: Generic modafinil 200 mg, Brand Provigil 200 mg	
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Quantity limit override requests must involve an FDA-approved indication.</p> <p style="text-align: center;">OR</p> <p>1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.</p> <p style="text-align: center;">AND</p> <p>2 - History of inadequate response to Provigil 200 mg/day</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:**</p> <p>3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information</p> <p style="text-align: center;">OR</p> <p>3.2 Higher dose or quantity is supported by one of following compendia:</p> <ul style="list-style-type: none"> • American Hospital Formulary Service Drug Information • Micromedex DRUGDEX System 	

Notes	Authorization will be issued for the length of therapy based on indication (Narcolepsy: 12 months, All other indications: 6 months). **NOTE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.
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Product Name: Generic armodafinil 150 mg, Brand Nuvigil 150 mg, Generic armodafinil 200 mg, Brand Nuvigil 200 mg, Generic armodafinil 250 mg, or Brand Nuvigil 250 mg

Guideline Type	Quantity Limit
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<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Quantity limit override requests must involve an FDA-approved indication.</p> <p style="text-align: center;">OR</p> <p>1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements.</p> <p style="text-align: center;">AND</p> <p>2 - One of the following**</p> <p>2.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information</p> <p style="text-align: center;">OR</p> <p>2.2 Higher dose or quantity is supported by one of following compendia</p> <ul style="list-style-type: none"> • American Hospital Formulary Service Drug Information • Micromedex DRUGDEX System 	
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Notes	Authorization will be issued for the length of therapy based on indication, except for titration purposes (Narcolepsy: 12 months, All other indications: 6 months). Not to exceed maximum FDA-approved dose. NO
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	TE: Published biomedical literature may be used as evidence to support safety and additional efficacy at higher than maximum doses for the diagnosis provided.
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Product Name: Brand Provigil 200mg, Generic modafinil 200mg	
Diagnosis	Narcolepsy: Twice-daily (BID) Therapy**
Approval Length	12 month(s)
Guideline Type	Quantity Limit
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [1,4,10,A-C]</p> <p style="text-align: center;">AND</p> <p>2 - One of the following</p> <p style="padding-left: 20px;">2.1 Trial and inadequate response to once daily treatment</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">2.2 A once daily treatment is not appropriate to treat the patient's condition</p> <p style="text-align: center;">AND</p> <p>3 - Requested dose does not exceed maximum dose range found in labeling or supported by one of the following off label compendia for the requested product:</p> <ul style="list-style-type: none"> • American Hospital Formulary Service Drug Information • Micromedex Drug System • Clinical research in two articles from major peer reviewed medical journals that present data supporting requested dose as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer-reviewed medical journal 	

Notes	**Requests for greater than twice-daily dosing must be reviewed using the Quantity Limit General Administrative Guideline.
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3 . Definitions

Definition	Description
Cataplexy [3]	A sudden loss of muscle tone that leads to feelings of weakness and a loss of voluntary muscle control.
CPAP (continuous positive airway pressure) [3]	Delivers pressurized air from a machine into airways through a specially designed mask that is worn during sleep.
Multiple sleep latency test (MSLT) [3]	Assesses the severity of sleepiness by measuring the speed of falling asleep during a series of nap trials.
Narcolepsy [3]	A neurological condition in which people experience excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations and intermittent, uncontrollable sleep attacks during the daytime.
Non-Rapid Eye Movement (NREM) sleep [3]	One of the two basic states of sleep; consists of Stages 1, 2 (light sleep) and 3,4 (deep sleep).
Obstructive sleep apnea (OSA) [3]	The most common kind of sleep apnea. It is caused by a blockage of the upper airway.
Polysomnography [3]	A test that records sleep architecture (i.e. the amount of NREM and REM sleep, number of arousals) and a variety of body functions during sleep, including breathing patterns, heart rhythms and limb movements. It is most commonly done to evaluate for sleep apnea.
Rapid Eye Movement (REM) sleep [3]	One of the two basic states of sleep. REM sleep, also known as "dream sleep," is characterized by rapid eye movements, and more irregular breathing and heart rate compared to NREM sleep.

4 . Endnotes

- A. The American Academy of Sleep Medicine guidelines list modafinil as a standard patient care strategy (generally accepted patient-care strategy that reflects a high degree of clinical certainty). [2]

- B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy with cataplexy (narcolepsy type 1) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. One or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT); or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than 110 pg/mL or one-third of the normative values with the same standardized assay). 3. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10,11]
- C. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy without cataplexy (narcolepsy type 2) include: 1. Daily periods of irrepressible need for sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) for at least 3 months. 2. Cataplexy is absent 3. CSF hypocretin-1 levels, if measured, must not meet the narcolepsy type 1 criterion. 4. A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques (a SOREMP within 15 minutes of sleep onset on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT). 5. Exclusion of alternative causes of chronic daytime sleepiness by history, physical exam, and polysomnography. Other conditions that cause chronic daytime sleepiness include insufficient sleep, untreated sleep apnea, periodic limb movements of sleep, and idiopathic hypersomnia (chronic sleepiness but without SOREMPs or other evidence of abnormal REM sleep). In addition, the effects of sedating medications should be excluded. [10.11]
- D. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for obstructive sleep apnea-hypopnea syndrome (OSAHS) include: One of the following: 1. PSG shows greater than or equal to 5 obstructive respiratory events per hour of sleep in a patient with one or more of the following: a. sleepiness, nonrestorative sleep, fatigue or insomnia symptoms b. waking up with breath holding, gasping or choking c. habitual snoring, breathing interruptions, or both noted by a bed partner or other observer d. hypertension, mood disorder, cognitive dysfunction, coronary artery disease, stroke, congestive heart failure, atrial fibrillation, or type 2 diabetes mellitus 2. Greater than or equal to 15 obstructive respiratory events per hour of sleep, regardless of the presence of associated symptoms or comorbidities. In addition, the disorder is not explained by another current sleep disorder, medical or neurological disorder, medication use, or substance use disorder. [10, F, G]
- E. Despite lack of good clinical evidence or statement/guideline from a professional society, use of modafinil for fatigue is considered the standard practice in MS patients [8].
- F. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [10].
- G. The effectiveness of modafinil (greater than 12 weeks for obstructive sleep apnea or SWD) and the effectiveness of armodafinil in long-term use (greater than 12 weeks) have not been systematically evaluated in placebo-controlled trials. [1,4]

5 . References

1. Provigil Prescribing Information. Teva Pharmaceuticals USA, Inc. North Wales, PA. July 2019.
2. Morgranthalder TI, Kapur VK, Brown T, et al. Practice parameters for the treatment of narcolepsy and other hypersomnias of central origin: An American Academy of Sleep Medicine report. *Sleep*. 2007 Dec;30(12):1705-11.
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6 . Revision History

Date	Notes
10/3/2023	2023 Annual Review

Quantity Limit General

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Prior Authorization Guideline

Guideline ID	GL-133855
Guideline Name	Quantity Limit General

Guideline Note:

Effective Date:	11/1/2023
P&T Approval Date:	5/20/2008
P&T Revision Date:	11/14/2019 ; 08/13/2020 ; 07/21/2021 ; 12/15/2021 ; 04/20/2022 ; 06/15/2022 ; 09/21/2022 ; 09/21/2022 ; 04/19/2023 ; 10/18/2023

Note:

For all other drugs subject to quantity limits, OptumRx may authorize coverage for additional quantities of medications listed on the Standard QL list for patients who meet the following criteria.

1 . Criteria

Product Name: Less than or equal to the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*	
Approval Length	12 Months (except for titration of loading-dose purposes)
Guideline Type	Administrative
Approval Criteria	

1 - One of the following:

1.1 Quantity limit override requests must involve an FDA-approved indication

OR

1.2 Quantity limit override requests involving off-label indications must meet off-label guideline approval criteria

AND

2 - One of the following:

2.1 For titration or loading-dose purposes (one time authorization or per FDA labeling)

OR

2.2 Requested strength/dose is commercially unavailable**

OR

2.3 Patient is on a dose alternating schedule

OR

2.4 For topical applications, patient requires a larger quantity to cover a larger surface area

Notes

Not to exceed maximum dose as specified in the product prescribing information or compendia for off-label uses. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day. *This guideline only applies in the absence of a drug-specific quantity limit override guideline. **Commercially available strength/dose requires a formulary drug.

Product Name: Greater than the maximum dose as specified in the product prescribing information (in the absence of a drug-specific guideline)*

Approval Length	12 month(s)
Guideline Type	Administrative
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Quantity limit override requests must involve an FDA-approved indication</p> <p style="text-align: center;">OR</p> <p>1.2 Quantity limit override requests involving off-label indications must meet off-label guideline requirements</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 The maximum doses specified under the quantity restriction have been tried for an adequate period of time and been deemed ineffective in the treatment of the member's disease or medical condition</p> <p style="text-align: center;">OR</p> <p>2.2 If lower doses have not been tried, there is clinical support (i.e., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the quantity restriction will be ineffective in the treatment of the member's disease or medical condition</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Higher dose or quantity is supported in the dosage and administration section of the manufacturer's prescribing information</p> <p style="text-align: center;">OR</p>	

<p>3.2 Higher dose or quantity is supported by one of following compendia:</p> <ul style="list-style-type: none"> • American Hospital Formulary Service Drug Information • Micromedex DRUGDEX System <p style="text-align: center;">OR</p> <p>3.3 Higher dose or quantity is supported by clinical research in two articles from major peer reviewed medical journals that present data supporting the proposed higher than maximum doses for the diagnosis provided as generally safe and effective</p>	
Notes	<p>*This guideline only applies in the absence of a drug-specific quantity limit override guideline. No override requests will be permitted for acetaminophen, alone or in combination with other agents, which will exceed a total of 4 grams of acetaminophen per day.</p>

2 . Revision History

Date	Notes
9/27/2023	Updated criteria for requested quantities that are less than or equal to the maximum dose as specified in the product prescribing information.

Regranex (becaplermin)

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Prior Authorization Guideline

Guideline ID	GL-127505
Guideline Name	Regranex (becaplermin)

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/16/2009
P&T Revision Date:	08/13/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Regranex Gel (becaplermin)
<p>Diabetic Neuropathic Ulcers Indicated for the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply, when used as an adjunct to, and not a substitute for, good ulcer care practices including initial sharp debridement, pressure relief and infection control. Limitations of Use: The efficacy of Regranex Gel has not been established for the treatment of pressure ulcers and venous stasis ulcers and has not been evaluated for the treatment of diabetic neuropathic ulcers that do not extend through the dermis into subcutaneous tissue (Stage I or II, IAET staging classification) or ischemic diabetic ulcers. The effects of becaplermin on exposed joints, tendons, ligaments, and bone have not been established in humans. Regranex is not intended to be used in wounds that close by primary intention.</p>

2 . Criteria

Product Name: Regranex

Approval Length	5 Months [1, A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient has a lower extremity diabetic neuropathic ulcer</p> <p style="text-align: center;">AND</p> <p>2 - Treatment will be given in combination with ulcer wound care (e.g., debridement, infection control, and/or pressure relief) [1]</p>	

3 . Endnotes

- A. Fifty percent of patients will achieve complete healing within 20 weeks with Regranex. Reassessment is required for further therapy. [1] If the ulcer does not decrease in size by approximately 30% after 10 weeks of treatment or complete healing has not occurred in 20 weeks, continued treatment with Regranex should be reassessed. Postmarketing studies have demonstrated an increased risk of mortality secondary to malignancy observed in patients treated with greater than or equal to 3 tubes of Regranex gel. [1]

4 . References

- 1. Regranex Prescribing Information. Smith & Nephew, Inc. Fort Worth, TX. August 2019.

5 . Revision History

Date	Notes
7/3/2023	Annual review: No criteria changes.

Restasis (cyclosporine 0.05%)

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Prior Authorization Guideline

Guideline ID	GL-107977
Guideline Name	Restasis (cyclosporine 0.05%)

Guideline Note:

Effective Date:	6/8/2022
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1 . Indications

Drug Name: Restasis (cyclosporine 0.05%) ophthalmic emulsion
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 . Criteria

Product Name: Brand Restasis, Generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

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

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

Product Name: Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion

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

1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

AND

2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

3 . Endnotes

- A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]
- B. The FDA-approved indication states that during clinical trials, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. [1]

4 . References

- 1. Restasis Prescribing Information. Allergan Inc. Irvine, CA. July 2017.
- 2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed May 28, 2021.

5 . Revision History

Date	Notes
6/8/2022	New EHB specific guideline.

Restasis (cyclosporine 0.05%) - PA, NF



Prior Authorization Guideline

Guideline ID	GL-103831
Guideline Name	Restasis (cyclosporine 0.05%) - PA, NF

Guideline Note:

Effective Date:	2/21/2022
P&T Approval Date:	10/26/2016
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 3/16/2022

1 . Indications

Drug Name: Restasis (cyclosporine 0.05%) ophthalmic emulsion
Keratoconjunctivitis sicca Indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

2 . Criteria

Product Name: Brand Restasis, Generic cyclosporine 0.05% ophthalmic emulsion (Tier 1*)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

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

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

Notes	NOTE: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 1 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 2 or Tier 3.
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Product Name: Generic cyclosporine 0.05% ophthalmic emulsion (Tier 2 or Tier 3*)	
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
Approval Criteria	

1 - One of the following:

1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)

OR

1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation

AND

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

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

AND

3 - All of the following:

3.1 At least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Documentation provided stating that brand Restasis has not been effective

AND

3.3 Justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

Notes	Note: *This criteria is to be used for generic cyclosporine 0.05% ophthalmic emulsion that is on Tier 2 or Tier 3 ONLY. This criteria does NOT apply to generic cyclosporine 0.05% ophthalmic emulsion on Tier 1.
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Product Name: Brand Restasis, generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Documentation of positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)</p> <p style="text-align: center;">AND</p> <p>2 - Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])</p>	

Product Name: Generic cyclosporine 0.05% ophthalmic emulsion	
Approval Length	12 month(s)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Diagnosis of moderate to severe keratoconjunctivitis sicca (dry eye)</p> <p style="text-align: center;">OR</p> <p>1.2 Diagnosis of Sjogren syndrome with suppressed tear production due to ocular inflammation</p>	

AND

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

2.1 Patient will not be using concurrent topical ophthalmic anti-inflammatory drugs (e.g., corticosteroids, NSAIDs [nonsteroidal anti-inflammatory drugs])

OR

2.2 Topical ophthalmic anti-inflammatory drugs will only be used concurrently for a short period (up to 8 weeks) while transitioning to monotherapy with the requested drug

AND

3 - All of the following:

3.1 Paid claims or submission of medical records (e.g., chart notes) confirming at least 6 months use of brand Restasis within the previous 365 days (document drug, duration, and date of use)

AND

3.2 Submission of documentation provided stating that brand Restasis has not been effective

AND

3.3 Submission of justification provided for why the generic is expected to provide benefit when brand Restasis has not been shown to be effective

3 . Endnotes

- A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in

addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

- B. The FDA-approved indication states that during clinical trials, increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs. [1]

4 . References

1. Restasis Prescribing Information. Allergan Inc. Irvine, CA. July 2017.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed May 28, 2021.

5 . Revision History

Date	Notes
2/18/2022	Update to include generic Restasis and addition of NF section

Riluzole Products - PA, NF

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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

Roszet (rosuvastatin/ezetimibe) - ST, NF



Prior Authorization Guideline

Guideline ID	GL-126401
Guideline Name	Roszet (rosuvastatin/ezetimibe) - ST, NF

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	6/16/2021
P&T Revision Date:	09/15/2021 ; 11/18/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Roszet (rosuvastatin/ezetimibe)
Non-familial hyperlipidemia Indicated as an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C).
Homozygous familial hypercholesterolemia (HoFH) Indicated alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

2 . Criteria

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (ST)	
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 one of the following generics:

- rosuvastatin
- atorvastatin 40 mg
- atorvastatin 80 mg

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	6 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 diagnoses:

- Non-familial hyperlipidemia
- Homozygous familial hypercholesterolemia (HoFH)

AND

2 - Submission of medical records (e.g., chart notes) documenting history of a trial and failure (of a minimum 30 day supply) or intolerance to two of the following:

- rosuvastatin
- atorvastatin
- simvastatin

AND

3 - Submission of medical records (e.g., chart notes) documenting history of trial and failure (of a minimum 30 day supply) or intolerance to ezetimibe

AND

4 - Physician has provided rationale for needing to use fixed-dose combination therapy with Roszet instead of taking individual products in combination

Product Name: Roszet, Brand Ezetimibe-Rosuvastatin (NF)	
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Submission of medical records (e.g., chart notes) documenting positive clinical response to therapy</p>	

3 . References

1. Roszet Prescribing Information. Althera Pharmaceuticals LLC. Morristown, NJ. June 2021.
2. Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol 2019; 73:e285-e350.
3. Cuchel M, Bruckert E, Ginsberg HN, et al. Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society. Eur Heart J. 2014;35:2146-57.

4 . Revision History

Date	Notes
6/7/2023	Annual Review - Update to t/f verbiage to remove "contraindication"

Rybelsus (semaglutide)



Prior Authorization Guideline

Guideline ID	GL-108264
Guideline Name	Rybelsus (semaglutide)

Guideline Note:

Effective Date:	6/17/2022
P&T Approval Date:	8/15/2019
P&T Revision Date:	12/18/2019 ; 01/15/2020 ; 01/20/2021 ; 01/19/2022 ; 5/19/2022

1 . Indications

Drug Name: Rybelsus (semaglutide)
<p>Type 2 diabetes mellitus Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: (1) RYBELSUS is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans. (2) RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. (3) RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus.</p>

2 . Criteria

Product Name: Rybelsus	
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 - Drug is not solely being used for weight loss

AND

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

- Metformin
- Metformin ER
- Glipizide-metformin
- Glyburide-metformin
- Pioglitazone-metformin

3 . References

1. American Diabetes Association. Standards of medical care in diabetes. Diabetes Care. 2022; 45 (suppl 1): S125-143.
2. Rybelsus Prescribing Information. Novo Nordisk A/S. Bagsvaerd, Denmark. September 2021.

4 . Revision History

Date	Notes
6/16/2022	Added exclusion criteria for weight loss.

Savella

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Prior Authorization Guideline

Guideline ID	GL-120841
Guideline Name	Savella

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	11/19/1999
P&T Revision Date:	12/18/2019 ; 03/18/2020 ; 03/17/2021 ; 04/21/2021 ; 10/20/2021 ; 02/17/2022 ; 2/16/2023

1 . Indications

Drug Name: Savella (milnacipran)
Fibromyalgia Indicated for the management of fibromyalgia. Savella is not approved for use in pediatric patients.

2 . Criteria

Product Name: Savella, Savella Titration Pack	
Approval Length	12 month(s)
Guideline Type	Step Therapy

<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure, contraindication, or intolerance to one of the following generics: [A]</p> <ul style="list-style-type: none"> • amitriptyline* • cyclobenzaprine* • duloxetine • gabapentin • pregabalin 	
Notes	*Amitriptyline and cyclobenzaprine are considered to be potentially inappropriate medications for use in patients 65 years of age and older. [2, A]

3 . Endnotes

- A. The 2019 Beers Criteria recommends avoiding the use of amitriptyline (independent of diagnosis or condition) and cyclobenzaprine in older adults due to their highly anticholinergic and sedating properties. [2] However, amitriptyline and cyclobenzaprine have strong evidence for efficacy in treating fibromyalgia. [3]

4 . References

1. Savella Prescribing Information. Allergan USA, Inc. Irvine, CA. September 2021.
2. American Geriatrics Society. American Geriatrics Society 2019 updated AGS Beers Criteria for potentially inappropriate medication use in older adults. J Am Geriatr Soc. 2019 Jan 29.
3. Clauw DJ. Fibromyalgia: a clinical review. JAMA. 2014 Apr 16;311(15):1547-55.

5 . Revision History

Date	Notes
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2/1/2023	Annual Review - no criteria changes
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Selzentry (maraviroc)



Prior Authorization Guideline

Guideline ID	GL-133082
Guideline Name	Selzentry (maraviroc)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	11/12/2013
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 04/20/2022 ; 11/17/2022 ; 11/16/2023

1 . Indications

Drug Name: Selzentry (maraviroc)
CCR5-tropic HIV-1 Indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 2 kg. Limitations of Use: Selzentry is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

2 . Criteria

Product Name: Brand Selzentry tablets, generic maraviroc 150mg and 300mg tablets, Selzentry solution	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 All of the following:

1.1.1 Diagnosis of CCR5-tropic HIV-1 infection as confirmed by a highly sensitive tropism assay

AND

1.1.2 Patient is currently taking or will be prescribed an optimized background antiretroviral therapy regimen

AND

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

OR

1.2 For continuation of prior therapy

3 . References

1. Selzentry Prescribing Information. ViiV Healthcare. Durham, NC. September 2022.
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. 2023. Available at <https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv>. Accessed September 14, 2023.

4 . Revision History

Date	Notes
11/20/2023	Annual review: no changes to criteria. background updates.

Sensipar (cinacalcet)



Prior Authorization Guideline

Guideline ID	GL-134277
Guideline Name	Sensipar (cinacalcet)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	10/4/2004
P&T Revision Date:	08/15/2019 ; 11/14/2019 ; 07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 07/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Sensipar (cinacalcet)
<p>Secondary Hyperparathyroidism Indicated for the treatment of secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis. Limitations of Use: Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia.</p> <p>Parathyroid Carcinoma Indicated for the treatment of hypercalcemia in adult patients with parathyroid carcinoma.</p> <p>Primary Hyperparathyroidism Indicated for the treatment of hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.</p>

2 . Criteria

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Secondary hyperparathyroidism [1-3]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older [1, A]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of secondary hyperparathyroidism with chronic kidney disease on dialysis</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication or intolerance to both of the following:</p> <ul style="list-style-type: none"> • A phosphate binder (e.g., PhosLo, Fosrenol, Renvela, Renagel, etc.) • A vitamin D analog (e.g., calcitriol, Hectorol, Zemplar, etc.) <p style="text-align: center;">AND</p> <p>4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)</p> <p style="text-align: center;">AND</p> <p>5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist</p>	

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Hypercalcemia with parathyroid carcinoma
Approval Length	12 Months [B]
Therapy Stage	Initial Authorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older [1, A]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of hypercalcemia with parathyroid carcinoma</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)</p> <p style="text-align: center;">AND</p> <p>4 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist</p>	

Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	Severe hypercalcemia with primary hyperparathyroidism [4-5]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient is 18 years of age or older [1, A]</p> <p style="text-align: center;">AND</p> <p>2 - Diagnosis of severe hypercalcemia (level greater than 1 mg/dL above the upper limit of normal) with primary hyperparathyroidism [C, D]</p>	

<p>AND</p> <p>3 - Patient is unable to undergo parathyroidectomy</p> <p>AND</p> <p>4 - Trial and failure or intolerance to generic cinacalcet (applies to brand Sensipar only)</p> <p>AND</p> <p>5 - Prescribed by or in consultation with an oncologist, endocrinologist, or nephrologist</p>
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Product Name: Brand Sensipar, generic cinacalcet	
Diagnosis	All diagnoses listed above
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy</p>	

3 . Endnotes

- A. Sensipar is not indicated for use in pediatric patients. In aggregate, pediatric clinical studies did not establish a safe and effective Sensipar dosing regimen for the pediatric population. Dosing with Sensipar in Pediatric Study 1 was stopped because of a fatality in a Sensipar-treated individual. The individual was noted to be severely hypocalcemic at the time of death. [1]
- B. In the pivotal study of Sensipar for parathyroid carcinoma, patients were treated with maintenance therapy for up to 48 weeks. [1]
- C. As recommended by an endocrinologist consultant, hypercalcemia is defined as serum calcium level greater than or equal to 12.5 mg/dL. [5]

- D. In the pivotal study of Sensipar for primary hyperparathyroidism, severe hypercalcemia was defined as a screening serum calcium level of > 12.5 mg/dL. The median exposure to Sensipar was 270 days (range: 32-1,105 days). [1]

4 . References

1. Sensipar prescribing information. Amgen Inc. Thousand Oaks, CA. December 2019.
2. Block GA, Martin KJ, de Francisco AL, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. N Engl J Med. 2004;350(15):1516-25.
3. Lindberg JS, Culleton B, Wong G, et al. Cinacalcet HCl, an oral calcimimetic agent for the treatment of secondary hyperparathyroidism in hemodialysis and peritoneal dialysis: a randomized, double-blind, multicenter study. J Am Soc Nephrol. 2005;16(3):800-7.
4. Peacock M, Bilezikian JP, Klassen PS, et al. Cinacalcet hydrochloride maintains long-term normocalcemia in patients with primary hyperparathyroidism. J Clin Endocrinol Metab. 2005;90(1):135-41.
5. Per clinical consult with endocrinologist, July 5, 2011.
6. Cinacalcet Prescribing Information. Actavis Pharma, Inc. Parsippany, NJ. August 2018.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes to clinical intent

SGLT2 Inhibitors



Prior Authorization Guideline

Guideline ID	GL-137130
Guideline Name	SGLT2 Inhibitors

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	12/18/2019 ; 12/18/2020 ; 12/18/2019 ; 05/14/2020 ; 05/14/2020 ; 06/17/2020 ; 08/14/2020 ; 06/16/2021 ; 10/20/2021 ; 12/15/2021 ; 04/20/2022 ; 05/19/2022 ; 07/20/2022 ; 05/18/2023 ; 08/17/2023 ; 09/20/2023 ; 12/13/2023

1 . Indications

Drug Name: Brenzavvy (bexagliflozin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Brenzavvy is not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus.
Drug Name: Invokamet (canagliflozin/metformin)
Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
Drug Name: Invokamet XR (canagliflozin/metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Canagliflozin is indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Invokana (canagliflozin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease (CVD). Indicated to reduce the risk of end-stage kidney disease (ESKD), doubling of serum creatinine, cardiovascular (CV) death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day. Limitations of use: Invokana is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Invokana is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m². INVOKANA is likely to be ineffective in this setting based upon its mechanism of action.

Drug Name: Qtern (dapagliflozin and saxagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: QTERN is not recommended for patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Segluromet (ertugliflozin and metformin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Steglatro (ertugliflozin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: Steglatro is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.

Drug Name: Steglujan (ertugliflozin and sitagliptin)

Type 2 Diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: Not recommended in patients with

type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Steglujan has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

Drug Name: Inpefa

Heart failure or Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors Indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: 1) heart failure, or 2) type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors

2 . Criteria

Product Name: Brand Bexagliflozin , Brenzavvy, Qtern, Segluromet, Steglatro, Steglujan, Invokamet, Invokamet XR, Invokana

Diagnosis	BEXAGLIFLOZIN
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Approval Length	12 month(s)
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Guideline Type	Step Therapy
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Approval Criteria

1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication

AND

2 - One of the following:

2.1 Trial and failure of a minimum 30-day supply, contraindication, or intolerance to one of the following generics:

- metformin
- metformin ER
- glipizide-metformin
- glyburide-metformin
- pioglitazone-metformin

OR

2.2 Patient has one of the following (Applies to Invokamet, Invokamet XR, and Invokana only):

- History of atherosclerotic cardiovascular disease (ASCVD)
- High risk for ASCVD with multiple risk factors (e.g., obesity, hypertension, smoking, dyslipidemia, albuminuria)
- Established chronic kidney disease (CKD)
- Heart failure

AND

3 - Trial and failure of a minimum 90 day supply, or intolerance to any one of the following preferred brands:

- Farxiga
- Xigduo XR

AND

4 - Trial and failure of a minimum 90 day supply, or intolerance to one of the following:

- Glyxambi
- Jardiance
- Synjardy
- Synjardy XR
- Trijardy XR

Product Name: Inpefa	
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 90 day supply, contraindication, or intolerance to one of the following:

- Farxiga
- Jardiance

3 . References

1. Invokana Prescribing Information. Janssen. Titusville, NJ. October 2022.
2. Invokamet Prescribing Information. Janssen. Titusville, NJ. October 2022.
3. Invokamet XR Prescribing information. Janssen Ortho, LLC. Titusville, NJ. October 2022.
4. Qtern Prescribing Information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. October 2022.
5. Segluromet Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. September 2021.
6. Steglatro Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. September 2021.
7. Steglujan Prescribing Information. Merck & Co., Inc. Whitehouse Station, NJ. September 2021.
8. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation*. 2017;136:e137–e161.
9. Maddox TM, Januzzi JL, Allen LA, et al. 2021 Update to the 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction. *J Am Coll Cardiol*. 2021;77 (6): 772–810.
10. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *Journal of Cardiac Failure*. Published online April 2022.
11. Brenzavvy Prescribing Information. TheracosBio, LLC. Marlborough, MA. July 2023.
12. Inpefa Prescribing Information. Lexicon Pharmaceuticals, Inc. The Woodlands, TX. May 2023.

4 . Revision History

Date	Notes
12/15/2023	Added Inpefa 400 mg to step therapy criteria and added Brand Bexa glicflozin to criteria as well.

Short-Acting Bronchodilators



Prior Authorization Guideline

Guideline ID	GL-121026
Guideline Name	Short-Acting Bronchodilators

Guideline Note:

Effective Date:	5/1/2023
P&T Approval Date:	11/13/2007
P&T Revision Date:	11/14/2019 ; 11/14/2019 ; 03/18/2020 ; 08/14/2020 ; 03/17/2021 ; 03/16/2022 ; 3/15/2023

1 . Indications

Drug Name: Proventil HFA (albuterol sulfate inhalation aerosol)
Bronchospasm Indicated in adults and children 4 years of age and older for the treatment or prevention of bronchospasm with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm.
Drug Name: Xopenex HFA (levalbuterol tartrate inhalation aerosol)
Bronchospasm Indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.
Drug Name: Ventolin HFA, Proair HFA (albuterol sulfate inhalation aerosol), Proair Digihaler (albuterol sulfate inhalation powder), Proair Resplick (albuterol sulfate powder)
Bronchospasm Indicated for the treatment of or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease.

Exercise-Induced Bronchospasm Indicated for the prevention of exercise-induced bronchospasm in patients 4 years of age and older.

2 . Criteria

Product Name: Proair Digihaler, Proair HFA, Proair Respiclick, Proventil HFA, Xopenex HFA, levalbuterol HFA, Ventolin HFA or Brand Albuterol HFA (Prasco manufacturer only, NDC 66993-0019-68)	
Approval Length	12 Months
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial of generic albuterol HFA</p>	

3 . References

1. Proventil HFA [prescribing information]. Whitehouse Station, NJ: Merck & Co. Inc; October 2019.
2. Xopenex HFA [prescribing information]. Marlborough, MA: Sunovion Pharmaceuticals Inc; February 2017.
3. Ventolin HFA [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
4. Proair HFA [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.
5. Proair Digihaler [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; December 2022.
6. Proair Respiclick [prescribing information]. Parsippany, NJ: Teva Respiratory, LLC; September 2022.

4 . Revision History

Date	Notes
2/23/2023	2023 UM Annual Review. No changes to clinical criteria. Updated background and references.

Skin Cancer Agents

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Prior Authorization Guideline

Guideline ID	GL-123435
Guideline Name	Skin Cancer Agents

Guideline Note:

Effective Date:	6/1/2023
P&T Approval Date:	4/10/2012
P&T Revision Date:	05/14/2020 ; 05/20/2021 ; 04/20/2022 ; 4/19/2023

1 . Indications

Drug Name: diclofenac sodium gel 3%
Actinic keratosis Indicated for the topical treatment of actinic keratoses. Sun avoidance is indicated during therapy.

2 . Criteria

Product Name: diclofenac sodium 3% gel	
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, contraindication, or intolerance to one of the following generics:

- imiquimod
- fluorouracil

3 . References

1. American Academy of Dermatology. Actinic Keratosis: diagnosis and treatment. <https://www.aad.org/public/diseases/scaly-skin/actinic-keratosis#treatment>. Accessed March 17, 2023.
2. Diclofenac sodium gel 3% Prescribing Information. Fort Collins, CO: Tolmar Inc.; June 2021.

4 . Revision History

Date	Notes
4/4/2023	Annual review - picato discontinued and will be obsolete 4/8/2023 - removed product. Updated background and references.

Soliqua (insulin glargine/ lixisenatide)

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Prior Authorization Guideline

Guideline ID	GL-126109
Guideline Name	Soliqua (insulin glargine/ lixisenatide)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	2/16/2017
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Soliqua 100/33 (insulin glargine and lixisenatide injection)
<p>Type 2 diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: SOLIQUA 100/33 has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. SOLIQUA 100/33 is not recommended for use in combination with any other product containing a GLP-1 receptor agonist. SOLIQUA 100/33 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. SOLIQUA 100/33 has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis. SOLIQUA 100/33 has not been studied in combination with prandial insulin.</p>

2 . Criteria

Product Name: Soliqua 100/33

Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one metformin-containing agent</p>	

3 . References

1. Soliqua Prescribing Information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. June 2022.

4 . Revision History

Date	Notes
6/12/2023	Annual review - added diagnosis statement and changed ST prerequisites to allow for any metformin-containing agent. Updated references.

State Mandate Reference Document



Prior Authorization Guideline

Guideline ID	GL-136661
Guideline Name	State Mandate Reference Document

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	
P&T Revision Date:	10/16/2019 ; 01/15/2020 ; 08/13/2020 ; 10/21/2020 ; 10/21/2020 ; 01/20/2021 ; 03/17/2021 ; 08/19/2021 ; 10/20/2021 ; 11/18/2021 ; 12/15/2021 ; 06/15/2022 ; 07/20/2022 ; 10/19/2022 ; 11/17/2022 ; 05/18/2023 ; 07/19/2023 ; 09/20/2023 ; 09/20/2023 ; 09/20/2023 ; 10/18/2023 ; 11/16/2023 ; 11/16/2023 ; 11/16/2023 ; 12/13/2023

Note:

**For Arkansas Criteria 2.3 ONLY - If a request for prior authorization is denied due to a step therapy requirement under this section, then Optum Rx shall authorize the preferred treatment required under the step therapy (if a prior authorization for the preferred treatment is required) without requiring the healthcare provider to submit a new or revised request.

1 . Criteria

Guideline Type	Administrative
Approval Criteria	

1 - For Arizona, (effective 12/31/2022), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

2 - The following mandates apply to Arkansas:

2.1 Effective 7/22/2015, all clinical criteria are deemed met when the medication is being used for pain control in someone who is terminally ill (defined as no expectation of recovery and death as a result of the illness or disease is reasonably expected within six [6] months).

OR

2.2 Effective 1/1/2022, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

2.3 Effective 8/1/2023, any clinical criteria component involving a trial/failure requirement are deemed met when either of the following are true:**

2.3.1 Request is for an antipsychotic prescription drug being used for the treatment of psychosis (a condition that affects the mind and affects the way the brain processes information, includes delusions and hallucinations) and serious mental illness (a mental, behavioral, or emotional disorder resulting in serious functional impairment, that substantially interferes with or limits one (1) or more major life activities)

OR

2.3.2 Request is for a drug to treat metastatic cancer (cancer that has spread from a primary or original site of the cancer to surrounding or nearby tissues, lymph nodes, or other parts of the body) UNLESS the preferred drug is consistent with best practices that are used for the treatment of metastatic cancer or associated conditions under FDA approved indication or NCCN Drugs and Biologics Compendium indication OR use evidence-based, peer-reviewed, recognized medical literature.

OR

2.4 Effective 7/31/2023, all clinical criteria are deemed met for buprenorphine, naloxone, naltrexone, methadone, and their various formulations and combinations approved by the United States Food and Drug Administration for the treatment or detoxification of opioid and alcohol addiction.

OR

3 - The following mandates apply to California:

3.1 Effective 1/1/2017, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication, it is appropriately prescribed, and that the medication is considered safe and effective in treating the patient's condition.

OR

3.2 Effective 7/1/1999 (applies to small group only), all clinical criteria are deemed met when the patient has previously been approved for coverage of the medication and the patient has had no reasonable break in therapy (i.e., last dose was within the last 60 days per claims history). The medication should be approved for the quantity the patient was previously taking as long as it is considered safe and effective for treating the medical condition.

OR

3.3 Effective 1/1/2022, step therapy requirements are deemed met if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient, based on medical necessity.

OR

4 - The following mandates apply to Colorado:

4.1 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

4.2 Effective 1/1/2023, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug is ineffective or was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

5 - The following mandates apply to Connecticut:

5.1 Effective 1/1/2012, step therapy may not be required for pain medications when a non AB rated alternative is required as first line.

OR

5.2 Effective 1/1/2015, only a 30 day trial of first step drugs will be required.

OR

5.3 Effective 1/1/2015, step therapy requirements are deemed met if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

5.4 Effective 1/1/2018, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

5.5 Effective 1/1/2024, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat schizophrenia, major depressive disorder, or bipolar disorder, as defined in the most recent edition of the American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders".

OR

6 - The following mandates apply to Delaware:

6.1 Effective 9/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

6.2 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

7 - For Florida, (effective 7/1/2023), any clinical criteria component involving a trial/failure requirement are deemed met when both of the following are true:

7.1 The provider attests that the patient has previously been approved to receive the prescription drug through the completion of a step-therapy protocol required by a separate health coverage plan.

AND

7.2 The provider attests that the health coverage plan paid for the prescription drug on the patient's behalf during the 90 days immediately before the request.

OR

8 - The following mandates apply to Georgia:

8.1 Effective 7/1/2015, all clinical criteria are deemed met when a patient is diagnosed as terminally ill and the medication requested is FDA-approved or meets off-label criteria for use directly related to the terminal illness. Terminal illness is defined as any disease, illness, or health condition that a physician has diagnosed and expected to result in death in 24 months or less.

OR

8.2 Effective 7/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

9 - The following mandates apply to Illinois:

9.1 Effective 1/1/2018, step therapy requirements are deemed met if the provider submits medical records confirming the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

9.2 Effective 1/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

9.3 Effective 6/9/2023, all clinical criteria are deemed met for intravenous immunoglobulin (IVIg) therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS).

OR

10 - For Indiana, (effective 7/1/2016), any clinical criteria component involving a trial/failure requirement are deemed met if any of the following apply:

10.1 A preceding prescription drug is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient.

OR

10.2 A preceding prescription drug is expected to be ineffective, based on the known clinical characteristics of the patient and known characteristics of the preceding prescription drug, as found in sound clinical evidence.

OR

10.3 The patient has previously received a preceding prescription drug or another prescription drug that is in the same pharmacologic class or has the same mechanism of action as a preceding prescription drug and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

OR

10.4 Based on clinical appropriateness, a preceding prescription drug is not in the best interest of the patient because the patient's use of the preceding prescription drug is expected to cause a significant barrier to the patient's adherence to or compliance with the patient's plan of care, worsen a comorbid condition of the patient, or decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities.

OR

11 - For Iowa, (effective 1/1/2018), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

12 - The following mandates apply to Kentucky:

12.1 Effective 7/12/2012, only a 30 day trial of first step drugs will be required.

OR

12.2 Effective 1/1/2023, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

12.3 Effective 1/1/2022, all clinical criteria for prospective or concurrent reviews are deemed met if the prescription drug is being used in the treatment of alcohol or opioid use disorder and contains methadone, buprenorphine, or naltrexone; or the prescription drug was approved before January 1, 2022 by the United States Food and Drug Administration for the mitigation of opioid withdrawal symptoms

OR

13 - The following mandates apply to Louisiana:

13.1 Effective 8/1/2019, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication, or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer, or the prescribed drug or drug regimen is supported by peer-reviewed, evidenced-based medical literature.

OR

13.2 Effective 1/1/2021, any clinical criteria component involving a trial/failure requirement are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

14 - The following mandates apply to Maine:

14.1 Effective 1/1/2020, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process,

all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, the required step one prescription drug is not in the best interest of the patient based on medical necessity, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

14.2 Effective 1/1/2022, all clinical criteria are deemed met when the medication is being prescribed to assess or treat the patient's serious mental illness, defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, as a mental disorder that results in serious functional impairment that substantially interferes with or limits one or more major life activities.

OR

15 - The following mandates apply to Maryland:

15.1 Effective 7/1/2015, step therapy requirements are deemed met if the provider submits medical records confirming the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient's condition.

OR

15.2 Effective 7/1/2015, step therapy requirements may not require trial of a drug that has not been approved by the U.S. Food and Drug Administration for the medical condition being treated.

OR

15.3 Effective 10/1/2017, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

15.4 Effective 1/1/2023, all clinical criteria are deemed met for rituximab and/or intravenous immunoglobulin (IVIg) therapy when the medication is being used for a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) or pediatric acute onset neuropsychiatric syndrome (PANS).

OR

15.5 Effective 1/1/2024, any clinical criteria component involving a trial/failure requirement are deemed met if any ONE of the following apply:

15.5.1 The prescription drug required by the tried/failed criteria is contraindicated or will likely cause an adverse reaction to the patient;

OR

15.5.2 The prescription drug required by the tried/failed criteria is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.

OR

15.5.3 The patient is stable on a prescription drug prescribed for the medical condition under consideration while covered under the policy or contract of the entity or under a previous source of coverage.

OR

15.5.4 While covered under the policy or contract of the entity or a previous source of coverage, the patient has tried a prescription drug that meets BOTH of the following:

- Is in the same pharmacologic class or has the same mechanism of action as the prescription drug required by the tried/failed criteria.
- Was discontinued by the prescriber due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

OR

16 - For Massachusetts, (effective 10/1/2023), any clinical criteria component involving a trial/failure requirement are deemed met if:

16.1 The prescription drug required by the tried/failed criteria is contraindicated or will likely cause an adverse reaction in or physical or mental harm to the patient.

OR

16.2 The prescription drug required by the tried/failed criteria is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen.

OR

16.3 The patient or prescribing provider has provided documentation establishing that the patient has previously tried the prescription drug required by the tried/failed criteria, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

OR

16.4 The patient or prescribing provider has provided documentation establishing that the patient is stable on a prescription drug prescribed by their provider and switching drugs will likely cause an adverse reaction in or physical or mental harm to the patient.

OR

17 - For Minnesota, (effective 1/1/2020), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

18 - For Nebraska, (effective 1/1/2022), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient or expected to be ineffective based on medical necessity.

OR

19 - The following mandates apply to Nevada:

19.1 Effective 1/1/2022, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage three or four cancer, or an associated condition, AND; the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

19.2 Effective 1/1/2024, any clinical criteria component (except step therapy) are deemed met when the medication is FDA approved to prevent the acquisition of HIV or to treat HIV or Hepatitis C.

OR

19.3 Effective 1/1/2024, any clinical criteria component involving a trial/failure requirement

are deemed met if the submitted prescriber statement and documentation demonstrate any ONE of the following:

19.3.1 The patient is stable on a prescription drug selected by his or her attending practitioner for the medical condition under consideration, regardless of whether the patient was covered by his or her current policy of health insurance at the time the prescriber selected the drug;

OR

19.3.2 Each prescription drug that is required to be used earlier in the trial/failure requirement is contraindicated or will likely cause an adverse reaction or physical or mental harm to the patient; is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the required prescription drug; has been tried by the patient regardless of whether the patient was covered by the current policy of health insurance at the time, and was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event relating to the prescription drug; or is not in the best interest of the patient, based on medical necessity.

OR

20 - The following mandates apply to New Mexico:

20.1 Effective 1/1/2019, when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria.

OR

20.2 Effective 7/1/2019, step therapy requirements are deemed met if the prescription drug requested is generic AND the required step one prescription drug is a therapeutically equivalent generic.

OR

20.3 Effective 1/1/2024, all clinical criteria are deemed met when the medication is being prescribed to treat the patient's mental health or substance use disorder and for acute or immediately necessary care, acute episodes of chronic conditions, or initial substance use treatment services.

OR

20.4 Effective 1/1/2024, all clinical criteria are deemed met if the medication is FDA approved, being prescribed for the treatment of a substance use disorder, and there is no generic version available.

OR

21 - For New York, (effective 1/1/2017), when the provider submits medical records confirming a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

22 - For North Dakota, (effective 8/5/2019), any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

23 - For Ohio, (effective 3/24/2021), any clinical criteria component involving a trial/failure

requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer, or consistent with best practices for the treatment of stage four advanced metastatic cancer, as supported by peer-reviewed medical literature.

OR

24 - The following mandates apply to Oklahoma:

24.1 Effective 11/1/2019, step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

24.2 Effective 11/1/2023, any clinical criteria component involving a trial/failure requirement are deemed met if the use of the prescription drug is consistent with best practices for the treatment of advanced metastatic cancer (cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body) or an associated condition (the symptoms or side effects associated with advanced metastatic cancer or its treatment and which, in the judgment of the health care practitioner, will further jeopardize the health of a patient if left untreated), supported by peer-reviewed, evidence-based literature, and approved by the United States Food and Drug Administration.

OR

25 - For Oregon, (effective 1/1/2022), when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication

for a period of at least 90 days for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

26 - The following mandates apply to Pennsylvania:

26.1 Effective 10/12/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or a severe adverse health condition experienced as a result of stage four metastatic cancer, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

26.2 Effective 1/1/2024, any clinical criteria component involving a trial/failure requirement are deemed met if each required prerequisite prescription drug is contraindicated including adverse reactions, if each required prerequisite prescription drug is expected to be ineffective, or if the patient has previously received a prerequisite prescription drug or another prescription drug that has the same mechanism of action as a prerequisite prescription drug and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

OR

27 - For South Dakota, (effective 1/1/2021), step therapy and non-formulary requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is not in the best interest of the patient based or expected to be ineffective based on medical necessity.

OR

28 - For Tennessee, (effective 1/1/2023), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the

requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity. Note: Samples and drugs obtained through coupon cards may not count as sufficient experience with the prescribed medication to be considered stable on the medication.

OR

29 - The following mandates apply to Texas:

29.1 Effective 1/1/2018, when the provider confirms that a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as a documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, and if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or cause harm to the patient, based on medical necessity.

OR

29.2 Effective 1/1/2020, any clinical criteria component involving a trial/failure requirement are deemed met if the prescription drug is used to treat the patient's stage four advanced metastatic cancer, or an associated condition, and treatment is consistent with the U.S. Food and Drug Administration-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer.

OR

29.3 Effective 1/1/2024, for a patient who is 18 years of age or older, any step therapy requirements for a drug used to treat serious mental illness, may not require:

29.3.1 For initial coverage: that a patient fails or prove a history of failure to more than one drug (excluding the generic or pharmaceutical equivalent of the prescribed drug).

OR

29.3.2 For continued coverage: that a patient fails or prove a history of failure of any drugs other than the generic or pharmaceutical equivalent if it is added to the plan's drug formulary.

OR

30 - For Vermont, (effective 1/1/2024), any clinical criteria component involving a trial/failure requirement, including a trial documented through a "MedWatch" (FDA Form 3500), are deemed met if the prescription drug is being used for the treatment of substance use disorder.

OR

31 - For Virginia, (effective 1/1/2020), step therapy requirements are deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

OR

32 - For Washington, (effective 1/1/2021), when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective or not in the best interest of the patient, based on medical necessity.

OR

33 - For West Virginia, (effective 1/1/2017), when the provider submits medical records confirming that a patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Step therapy requirements are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration.

OR

34 - For Wisconsin, (effective 11/1/2019), any clinical criteria component involving a trial/failure requirement are deemed met when the provider confirms a patient has previously received either a documented step one prescription drug or submits medical records documenting another prescription drug was received that has the same mechanism of action as the documented step one prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event, the patient will not be required to try any other alternatives within the same pharmacological class or with the same mechanism of action. Where documented step one prescription drugs are deemed met due to this process, all documented step one prescription drugs with the same mechanism of action will count towards the number of alternatives to be tried/failed. If step through other prescription drugs with a different mechanism of action is still required, the patient must meet the additional criteria. Any clinical criteria component involving a trial/failure requirement are also deemed met if the provider submits medical records confirming that the patient is currently stabilized on the requested medication for the medical condition under consideration, or if submitted justification and clinical documentation support that the required step one prescription drug is expected to be ineffective.

2 . Background

Benefit/Coverage/Program Information

Background:

This document serves as a reference for changes requested to pharmacy utilization management programs based on state mandates. This includes but is not limited to step

therapy, prior authorization regulations, supply limits, first line trial duration limitations, and pain therapy/end of life regulations.

Additional Clinical Rules:

- Applicable clinical programs will apply.

3 . Revision History

Date	Notes
12/4/2023	Criteria update

Sunosi (solriamfetol)



Prior Authorization Guideline

Guideline ID	GL-134281
Guideline Name	Sunosi (solriamfetol)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	6/19/2019
P&T Revision Date:	01/15/2020 ; 05/14/2020 ; 05/19/2022 ; 11/17/2022 ; 05/18/2023 ; 5/18/2023

1 . Indications

Drug Name: Sunosi (solriamfetol)
<p>Narcolepsy Indicated to improve wakefulness in adults patients with excessive daytime sleepiness associated with narcolepsy.</p> <p>Obstructive sleep apnea (OSA) Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with obstructive sleep apnea (OSA). Limitations of use: Sunosi is not indicated to treat the underlying airway obstruction in OSA. Ensure that the underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP)) for at least one month prior to initiating Sunosi for excessive daytime sleepiness. Modalities to treat the underlying airway obstruction should be continued during treatment with Sunosi. Sunosi is not a substitute for these modalities.</p>

2 . Criteria

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [A, B]</p> <p style="text-align: center;">AND</p> <p>2 - BOTH of the following;</p> <p>2.1 Trial and failure, contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> • generic modafinil • generic armodafinil <p style="text-align: center;">AND</p> <p>2.2 ONE of the following:</p> <p>2.2.1 Trial and failure, contraindication, or intolerance to an amphetamine (e.g., amphetamine, dextroamphetamine) or methylphenidate based stimulant</p> <p style="text-align: center;">OR</p> <p>2.2.2 History of or potential for a substance use disorder</p>	

Product Name: Sunosi	
Diagnosis	Narcolepsy
Approval Length	12 month(s)
Therapy Stage	Reauthorization

Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy.</p>	

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of obstructive sleep apnea defined by one of the following: [4]</p> <p> 1.1 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]</p> <p style="text-align: center;">OR</p> <p> 1.2 Both of the following:</p> <p> 1.2.1 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible) [C]</p> <p style="text-align: center;">AND</p> <p> 1.2.2 One of the following signs/symptoms are present:</p> <ul style="list-style-type: none"> • Daytime sleepiness • Nonrestorative sleep • Fatigue • Insomnia • Waking up with breath holding, gasping, or choking 	

- Habitual snoring noted by a bed partner or other observer
- Observed apnea

AND

2 - Both of the following:

2.1 Standard treatment(s) for the underlying obstruction (e.g., with continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP]) have been used for one month or longer

AND

2.2 Patient is fully compliant with ongoing treatment(s) for the underlying airway obstruction

AND

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

- generic modafinil
- generic armodafinil

Product Name: Sunosi	
Diagnosis	Obstructive Sleep Apnea (OSA)
Approval Length	6 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy.</p> <p style="text-align: center;">AND</p>	

2 - Patient continues to be fully compliant with ongoing treatment(s) for the underlying airway obstruction (e.g., CPAP, BiPAP)

3 . Endnotes

- A. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 1 (narcolepsy with cataplexy) require: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) The presence of one or both of the following: cataplexy and a mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT; or cerebrospinal fluid (CSF) hypocretin-1 concentration is low (less than or equal to 110 pg/mL or less than one-third of mean values obtained in normal subjects with the same standardized assay) [2,3].
- B. International Classification of Sleep Disorders (ICSD-3) diagnostic criteria for narcolepsy type 2 (narcolepsy without cataplexy) include: 1) Daily periods of irrepressible need to sleep or daytime lapses into sleep (i.e., excessive daytime sleepiness) occurring for at least 3 months. 2) Cataplexy is absent. 3) CSF hypocretin-1 levels, if measured, is either greater than 100 pg/mL or greater than one-third of mean values obtained in normal subjects with the same standardized assay. 4) A mean sleep latency of less than or equal to 8 minutes and 2 or more sleep onset REM periods (SOREMPs) on a multiple sleep latency test (MSLT) performed using standard techniques. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace 1 of the SOREMPs on the MSLT. 5) Hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, obstructive sleep apnea, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal [2,3].
- C. Examples of obstructive respiratory events include: obstructive and mixed apneas, hypopneas, or respiratory effort related arousals (RERA) [2].

4 . References

- 1. Sunosi Prescribing Information. Jazz Pharmaceuticals, Inc. Palo Alto, CA. October 2021.
- 2. Sateia MJ. International classification of sleep disorders - third edition: highlights and modifications. CHEST. 2014 Nov;146(5):1387-1394.
- 3. UpToDate. Clinical features and diagnosis of narcolepsy. Available by subscription at: https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-narcolepsy-in-adults?search=Clinical%20features%20and%20diagnosis%20of%20narcolepsy&source=search_result&selectedTitle=1~116&usage_type=default&display_rank=1. Accessed March 30, 2020.
- 4. UpToDate. Clinical presentation and diagnosis of obstructive sleep apnea in adults. Available by subscription at: <https://www.uptodate.com/contents/clinical-presentation-and-diagnosis-of-obstructive-sleep-apnea-in->

adults?search=obstructive%20sleep%20apnea&source=search_result&selectedTitle=4~150&usage_type=default&display_rank=4. Accessed March 30, 2020.

5 . Revision History

Date	Notes
10/4/2023	Program update to standard reauthorization language. No changes to clinical intent

Tadalafil

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Prior Authorization Guideline

Guideline ID	GL-126217
Guideline Name	Tadalafil

Guideline Note:

Effective Date:	9/1/2023
P&T Approval Date:	7/18/2018
P&T Revision Date:	07/15/2020 ; 07/21/2021 ; 07/20/2022 ; 7/19/2023

1 . Indications

Drug Name: Generic tadalafil
<p>Benign Prostatic Hyperplasia (BPH) and Erectile Dysfunction (ED) Indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) and for the treatment of erectile dysfunction (ED) and the signs and symptoms of BPH (ED/BPH). Limitation of use: If Cialis is used with finasteride to initiate BPH treatment, such use is recommended for up to 26 weeks because the incremental benefit of Cialis decreases from 4 weeks until 26 weeks, and the incremental benefit of Cialis beyond 26 weeks is unknown.</p>

2 . Criteria

Product Name: Generic tadalafil 2.5 mg or generic tadalafil 5 mg	
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria	
1 - Diagnosis of benign prostatic hyperplasia (BPH)	
Notes	Quantity limit: Cialis (tadalafil) 2.5 mg and 5 mg tablets will be subject to a quantity limit of 1 tablet per day.

3 . References

1. Tadalafil Prescribing Information. Ajanta Pharma USA Inc. Bridgewater, NJ. May 2023.

4 . Revision History

Date	Notes
7/28/2023	Annual Review

Testosterone



Prior Authorization Guideline

Guideline ID	GL-135336
Guideline Name	Testosterone

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/17/2005
P&T Revision Date:	11/14/2019 ; 02/13/2020 ; 02/13/2020 ; 04/15/2020 ; 04/21/2021 ; 03/16/2022 ; 05/19/2022 ; 09/21/2022 ; 08/18/2022 ; 09/21/2022 ; 11/17/2022 ; 01/18/2023 ; 02/16/2023 ; 03/15/2023 ; 04/19/2023 ; 7/19/2023

1 . Indications

Drug Name: Androderm (testosterone [T] patch), Androgel (T gel and pump), Fortesta (T gel), Natesto (T nasal gel), Testim (T gel), and Vogelxo (T gel and pump)

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy or toxic damage from alcohol or heavy metals. These men usually have low testosterone serum levels and gonadotropins (FSH, LH) above the normal range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or

pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Important limitations of use: Safety and efficacy in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy in males less than 18 years old have not been established. Topical testosterone products may have different doses, strengths, or application instructions that may result in different systemic exposure.

Drug Name: Methitest (methyltestosterone) tablet

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Metastatic mammary cancer in females Indicated for secondary use in women with advancing inoperable metastatic (skeletal) mammary cancer who are 1 to 5 years postmenopausal. Primary goals of therapy in these women include ablation of the ovaries. Other methods of counteracting estrogen activity are adrenalectomy, hypophysectomy, and/or antiestrogen therapy. This treatment has also been used in premenopausal women with breast cancer who have benefited from oophorectomy and are considered to have a hormone-responsive tumor. Judgment concerning androgen therapy should be made by an oncologist with expertise in this field.

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsions, orchitis, vanishing testis syndrome, or orchidectomy.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) is idiopathic gonadotropin or LHRH deficiency, or pituitary hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Drug Name: Depo-Testosterone (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchidectomy. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Safety and efficacy of Depo-Testosterone (testosterone cypionate) in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Testopel (testosterone) pellet

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, or orchiectomy. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired)- idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty. Safety and efficacy of Testopel in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Delayed puberty in males Indicated for stimulation of puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be obtained every six months to assess the effect of treatment on the epiphyseal centers.

Drug Name: Aveed (testosterone undecanoate) injection

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired): testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired): idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Aveed should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis. Limitations of use: Safety and efficacy of Aveed in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. Safety and efficacy of Aveed in males less than 18 years old have not been established.

Drug Name: Testone CIK (testosterone cypionate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome; or orchidectomy. Limitations of Use: Safety and efficacy of testosterone cypionate in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - idiopathic gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. Limitations of Use: Safety and efficacy of testosterone cypionate in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.

Drug Name: Xyosted (testosterone enanthate) injection

Primary hypogonadism (congenital or acquired) Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Primary hypogonadism (congenital or acquired) - Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (FSH, LH) above the normal range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for replacement

therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. Hypogonadotropic hypogonadism (congenital or acquired) - Gonadotropin or LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Safety and efficacy of Xyosted in males less than 18 years old have not been established.

Drug Name: Jatenzo (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Jatenzo in males less than 18 years old have not been established.

Drug Name: Tlando (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Tlando in males less than 18 years old have not been established.

Drug Name: Kyzatrex (testosterone undecanoate) capsule

Primary hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) is testicular failure due to

cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Hypogonadotropic hypogonadism (congenital or acquired) Indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Hypogonadotropic hypogonadism (congenital or acquired) is gonadotropin or luteinizing hormone releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. Limitations of Use: Safety and efficacy of Kyzatrex in males less than 18 years old have not been established.

Drug Name: Androderm, Androgel, Aveed, Depo-Testosterone, Fortesta, Methitest, Natesto, Testone CIK, Testim, Testopel, Vogelxo, Xyosted

Off Label Uses: Transgender male (female-to-male) - Gender Dysphoria/Gender Incongruence [11-12, 17, 28-29] Testosterone in 3 different formulations, including transdermal gel, significantly increased testosterone levels from the physiological range for women to the normal male range by week 30 of treatment in an observational study in transgender male (female-to-male) individuals. Hormonal sex reassignment therapy was associated with significantly fewer symptoms related to social distress, anxiety, and depression compared with those not receiving hormonal therapy in 1 cross-sectional study. Gender transition treatment can be initiated in adults and adolescents with confirmed persistent gender dysphoria/gender incongruence who have the capacity to make fully informed decisions and consent, usually by age 16 years, and have well-controlled, if any, mental health concerns. The goals of therapy are to suppress endogenous sex hormones of the designated gender and to replace these with endogenous sex hormones of the affirmed gender. Either parenteral or transdermal testosterone may be used to achieve and maintain testosterone levels in the normal male range. Avoid sustained supraphysiologic levels to reduce risk of adverse reactions. Compelling reasons may exist to initiate therapy at younger than 16 years; although, studies in this population are minimal. Initial therapy to undergo suppression of pubertal development at Tanner stages G2/B2 is suggested. Neither puberty suppression nor gender-affirming hormone therapies are recommended in pre-pubertal children.

2 . Criteria

Product Name: Androderm, Brand Androgel gel and pump (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Natesto, Generic testosterone gel 25 mg/2.5 g (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone gel pump (1%), Generic testosterone topical solution 30 mg/act, Generic testosterone gel 10 mg/act (2%), Aveed, Generic testosterone enanthate, Brand

Depo-Testosterone, Brand Fortesta, Brand Testim, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Xyosted, Brand Vogelxo	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p> <p style="text-align: center;">AND</p> <p>3 - Patient is 18 years of age or older</p> <p style="text-align: center;">AND</p> <p>4 - One of the following:</p> <p style="padding-left: 20px;">4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 9]</p> <p style="text-align: center;">OR</p> <p style="padding-left: 20px;">4.2 Both of the following:</p> <p style="padding-left: 40px;">4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)</p>	

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

5 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

6 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

7 - Trial and failure or intolerance to generic testosterone gel (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, and Brand Natesto only)

Notes	**This may require treatment to be temporarily held.
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Product Name: Generic testosterone cypionate	
Diagnosis	Male hypogonadism
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p>	

AND

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab**

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

Notes	**This may require treatment to be temporarily held.
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Product Name: Methitest, Generic methyltestosterone, Jatenzo, Kyzatrex, Tlando	
Diagnosis	Male hypogonadism
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of hypogonadism (e.g., testicular hypofunction, male hypogonadism)</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p> <p style="text-align: center;">AND</p>	

3 - Patient is 18 years of age or older

AND

4 - One of the following:

4.1 Two pre-treatment serum total testosterone levels less than 300 ng/dL (< 10.4 nmol/L) or less than the reference range for the lab*** [7, 8]

OR

4.2 Both of the following:

4.2.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

4.2.2 One pre-treatment calculated free or bioavailable testosterone level less than 5 ng/dL (< 0.17 nmol/L) or less than the reference range for the lab***

OR

4.3 Patient has a history of one of the following:

- Bilateral orchiectomy
- Panhypopituitarism
- A genetic disorder known to cause hypogonadism (e.g., congenital anorchia, Klinefelter's syndrome)

OR

4.4 Both of the following:

4.4.1 Patient is continuing testosterone therapy

AND

4.4.2 One of the following:

4.4.2.1 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is within or below the normal limits of the reporting lab

OR

4.4.2.2 Follow-up total serum testosterone level or calculated free or bioavailable testosterone level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

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

- Androderm (testosterone patch)
- Generic testosterone gel

Notes	***This may require treatment to be temporarily held.
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Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2%), Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted

Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	6 months for patients new to testosterone therapy; or 12 months for patients continuing testosterone therapy but without a current authorization on file with OptumRx [B]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

AND

3 - Trial and failure or intolerance to both of the following (applies to Aveed, Testopel, Testosterone implant pellets, Testone CIK, Brand Depo-Testosterone, Brand Testosterone Cypionate):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

4 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

AND

5 - Trial and failure or intolerance to generic testosterone (applies to Brand Androgel, Brand Fortesta, Brand Testim, Brand Vogelxo, Brand Natesto only)

Product Name: Generic testosterone cypionate	
Diagnosis	Gender Dysphoria/Gender Incongruence (off-label) [11-12, 17, 26 D]
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of gender dysphoria/gender incongruence [11-12, 17, 26]

AND

2 - Using hormones to change characteristics to align with gender expression [11, 17, 28-29]

Product Name: Androderm, Brand Androgel gel and pump (1%), Generic testosterone gel 25 mg/2.5 g (1%), Brand Androgel gel and pump (1.62%), Generic testosterone gel and pump 20.25 mg/1.25 g, 40.5 mg/2.5 g (1.62%), Generic testosterone topical solution 30 mg/act, Brand Fortesta, Generic testosterone gel 10 mg/act (2%), Jatenzo, Kyzatrex, Methitest, Natesto, Brand Testim, Generic methyltestosterone, Brand Vogelxo gel and pump (1%), Generic testosterone gel 50 mg/5 g (1%), Generic testosterone pump (1%), Aveed, Generic testosterone enanthate, Brand Depo-Testosterone, Brand Testosterone Cypionate, Generic testosterone cypionate, Testone CIK, Testopel, Testosterone implant pellets, Tlando, Xyosted

Diagnosis	Male hypogonadism, Gender dysphoria/Gender incongruence
Approval Length	12 Month [B]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.2 Follow-up total serum testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

OR

1.3 Both of the following:

1.3.1 Patient has a condition that may cause altered sex-hormone binding globulin (SHBG) (e.g., thyroid disorder, HIV disease, liver disorder, diabetes, obesity)

AND

1.3.2 One of the following:

1.3.2.1 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is within or below the normal limits of the reporting lab

OR

1.3.2.2 Follow-up calculated free or bioavailable testosterone level drawn within the past 6 months for patients new to testosterone therapy, or 12 months for patients continuing testosterone therapy, is outside of upper limits of normal for the reporting lab and the dose is adjusted

AND

2 - Trial and failure or intolerance to one of the following (applies to Xyosted only):

- Generic testosterone cypionate
- Generic testosterone enanthate

Product Name: Methitest, Generic testosterone enanthate, Testopel, Testosterone implant pellets, Generic methyltestosterone, Brand Testosterone Cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	6 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of delayed puberty [A]

AND

2 - Male patient at birth [C]

AND

3 - Trial and failure or intolerance to both of the following (applies to Testopel and Testosterone implant pellets only):

- Generic testosterone cypionate [F]
- Generic testosterone enanthate

Product Name: Generic testosterone cypionate [off-label]	
Diagnosis	Delayed puberty [E]
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of delayed puberty [A]</p> <p style="text-align: center;">AND</p> <p>2 - Male patient at birth [C]</p>	

Product Name: Methitest, Generic methyltestosterone, Generic testosterone enanthate	
Diagnosis	Inoperable breast cancer in women

Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of breast cancer</p> <p style="text-align: center;">AND</p> <p>2 - Breast cancer is inoperable</p> <p style="text-align: center;">AND</p> <p>3 - Used for palliative treatment</p> <p style="text-align: center;">AND</p> <p>4 - Female patient at birth [C]</p>	

3 . Endnotes

- A. Delayed puberty is defined as the lack of the initial signs of sexual maturation by an age that is more than 2-2.5 standard deviations above the mean for the population (traditionally, the age of 14 years in boys and 13 years in girls). In most cases, delayed puberty is not due to an underlying pathology, but instead represents an extreme end of the normal spectrum of pubertal timing, a developmental pattern referred to as constitutional delay of growth and puberty (CDGP). CDGP is the most common cause of delayed puberty in both sexes, but it can be diagnosed only after underlying conditions have been ruled out. Management of CDGP may involve expectant observation or therapy with low-dose sex steroids. [9]
- B. Initial authorization of 6 months, and reauthorization of 12 months is based on the Endocrine Society's Clinical Practice Guideline's recommendation to monitor testosterone level 3 to 6 months after initiation of testosterone therapy, and then annually to assess whether symptoms have responded to treatment and whether the patient is suffering from any adverse effects. [8]
- C. The gender criteria in place for male hypogonadism, delayed puberty, and inoperable breast cancer are to ensure safe and effective medication utilization due to FDA-approved labeling supporting the gender restriction [refer to individual Package Inserts].

Age and/or gender criteria will remain in the guideline, consistent with the following direction approved by OptumRx Legal & Regulatory: "Age and gender edits in place due to FDA safety guidance, labeling or supported by medical literature to satisfy medical necessity criteria would not be inconsistent with the [Section 1557 HCR non-discrimination] regulation."

- D. According to DRUGDEX, for the treatment of transgender male (female-to-male) patients with gender dysphoria, various forms and dosages of testosterone have been used. [12] Clinical studies have also demonstrated the efficacy of several different androgen preparations to induce masculinization in female-to-male transgender persons. Regimens to change secondary sex characteristics follow the general principle of hormone replacement treatment of male hypogonadism. Either parenteral or transdermal preparations can be used to achieve testosterone values in the normal male range. [11]
- E. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal center [19-20].
- F. Per consult with specialist, the pharmacokinetics of T. cypionate and T. enanthate are quite similar and physiologically produce similar results. The two agents are very close in efficacy and behavioral effects. Although T. cypionate isn't FDA-approved for delayed puberty, it is used in practice due to its similarity to T. enanthate. [25]

4 . References

1. Androderm Prescribing Information. Allergan Inc. Madison, NJ. May 2020.
2. Androgel Prescribing Information. Abbvie, Inc. North Chicago, IL. May 2019.
3. Androgel 1.62% Prescribing Information. AbbVie Inc. North Chicago, IL. February 2019.
4. Fortesta Prescribing Information. Endo Pharmaceuticals. Malvern, PA. June 2020.
5. Methitest Prescribing Information. Amneal Pharmaceuticals LLC. Bridgewater, NJ. October 2018.
6. Testim Prescribing Information. Endo Pharmaceuticals Inc. Malvern, PA. August 2021.
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8. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2018; 103(5):1715-1744.
9. Palmert MR, Dunkel L. Clinical practice. Delayed puberty. N Engl J Med. 2012; 366(5):443-53.
10. Vogelxo Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. April 2020.
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15. Testosterone Pump Prescribing Information. Upsher-Smith Laboratories, Inc. Maple Grove, MN. July 2017.

16. Methyltestosterone Prescribing Information. Impax Generics. Hayward, CA. January 2017.
17. Coleman E, Bockting W, Botzer M et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. International Journal of Transgenderism. 13:165-232, 2011.
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22. Testone CIK Prescribing Information. Asclemed USA, Inc. Torrance, CA. November 2018.
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27. Tlando Prescribing Information. Antares Pharma, Inc. Ewing, NJ. March 2022.
28. Deutsch, MB, Amato P, Coureu M, et al. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. UCSF Gender Affirming Health Program, Department of Family and Community Medicine, University of California San Francisco. June 2016
29. Health Care for Transgender and Gender Diverse Individuals: ACOG Committee Opinion, Number 823. American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice.137(3):e75-e88, 2021
30. Kyzatrex Prescribing Information. Marius Pharmaceuticals. Raleigh, NC. July 2022.

5 . Revision History

Date	Notes
10/25/2023	Update Xyosted criteria to require t/f/c/i to generic testosterone cypionate OR generic testosterone enanthate

Tier Lowering Exceptions Process

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Prior Authorization Guideline

Guideline ID	GL-133360
Guideline Name	Tier Lowering Exceptions Process

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	5/28/2014
P&T Revision Date:	11/14/2019 ; 11/12/2020 ; 11/18/2021 ; 11/17/2022 ; 11/16/2023

Note:

The intent of this policy is to serve as guidance for clients who would like to implement a Tier Lowering program.

1 . Criteria

Product Name: Tier Lowering Exceptions Process	
Approval Length	12 month(s)
Guideline Type	Administrative
Approval Criteria 1 - A prescribed drug will be considered for coverage under the prescribed drug's lower tier when one of the following are met:	

1.1 All lower-tiered medication alternatives would be less effective or have been demonstrated to be ineffective for treating the patient’s condition when used at optimized dose and frequency

OR

1.2 All lower-tiered medication alternatives would have adverse effects (intolerance or contraindication) in the treatment of the patient’s condition.

2 . Revision History

Date	Notes
11/1/2023	Annual review: No updates required.

Topical Antifungals - PA, NF



Prior Authorization Guideline

Guideline ID	GL-118870
Guideline Name	Topical Antifungals - PA, NF

Guideline Note:

Effective Date:	4/1/2023
P&T Approval Date:	2/15/2016
P&T Revision Date:	02/13/2020 ; 12/16/2020 ; 02/18/2021 ; 02/17/2022 ; 09/21/2022 ; 12/14/2022 ; 2/16/2023

1 . Indications

Drug Name: Ciclopirox Kit (ciclopirox)
Onychomycosis Indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to <i>Trichophyton rubrum</i> . The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures.
Drug Name: Jublia (efinaconazole) topical solution
Onychomycosis of the toenails Indicated for the topical treatment of onychomycosis of the toenail(s) due to <i>Trichophyton rubrum</i> and <i>Trichophyton mentagrophytes</i> .
Drug Name: Kerydin (tavaborole) topical solution
Onychomycosis of the toenails Indicated for the treatment of onychomycosis of the toenails due to <i>Trichophyton rubrum</i> or <i>Trichophyton mentagrophytes</i> .

2 . Criteria

Product Name: Ciclopirox Kit	
Diagnosis	Fingernail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of onychomycosis of the fingernail(s)</p> <p style="text-align: center;">AND</p> <p>2 - The patient does not have dermatophytomas or lunula (matrix) involvement</p> <p style="text-align: center;">AND</p> <p>3 - Diagnosis of fingernail onychomycosis has been confirmed by one of the following:</p> <ul style="list-style-type: none"> • Positive potassium hydroxide (KOH) preparation • Culture • Histology <p style="text-align: center;">AND</p> <p>4 - Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine [B]</p>	

Product Name: Ciclopirox Kit, Generic tavaborole, Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

Product Name: Brand Kerydin	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of onychomycosis of the toenail(s)</p>	

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Both of the following:

5.1 Trial and failure, contraindication (of a minimum 12-week supply), or intolerance to oral terbinafine [B]

AND

5.2 Trial and failure (of a minimum 48-week supply), contraindication, or intolerance to generic tavaborole

Product Name: Jublia	
Diagnosis	Toenail Onychomycosis
Approval Length	48 Weeks [3, 6, A]
Guideline Type	Non Formulary

Approval Criteria

1 - Diagnosis of onychomycosis of the toenail(s)

AND

2 - The patient does not have dermatophytomas or lunula (matrix) involvement

AND

3 - Diagnosis of toenail onychomycosis has been confirmed by one of the following:

- Positive potassium hydroxide (KOH) preparation
- Culture
- Histology

AND

4 - Patient has mild to moderate disease involving at least one target toenail

AND

5 - Treatment is requested due to a documented medical condition and not for cosmetic purposes (e.g. patients with history of cellulitis of the lower extremity, patients with diabetes who have additional risk factors for cellulitis of lower extremity, patients who experience pain/discomfort associated with the infected nail)

AND

6 - One of the following:

6.1 Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ciclopirox

OR

6.2 Patient is 6 to 12 years of age

AND

7 - Paid claims or submission of medical records (e.g., chart notes) confirming history of failure, contraindication, or intolerance to 12 weeks of treatment with ONE of the following oral antifungal agents:

- itraconazole
- terbinafine
- griseofulvin

3 . Endnotes

- A. Considering that toenails can take 12 to 18 months to grow out, many clinicians consider that 1 year is too short to assess clinical effectiveness. [4] Reports of long-term follow-up of treated patients have been presented, suggesting that positive mycology at 12 and 24 weeks after commencement of therapy are poor prognostic signs and may indicate a need for retreatment or for a change of drug. [5]
- B. Oral terbinafine has been shown to have superior efficacy compared to topical treatments and is recommended as first-line therapy for onychomycosis. [4, 6, 7] Compared to itraconazole, terbinafine has been found to have lower long-term mycological recurrence rates and better tolerability. [4, 6]

4 . References

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2. Kerydin prescribing information. PharmaDerm, a division of Fougera Pharmaceuticals, Inc. Melville, NY. August 2018.
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8. Tavorole prescribing information. Alembic Pharmaceuticals, Inc. Bridgewater, NJ. November 2021.

5 . Revision History

Date	Notes
1/25/2023	2023 UM Annual Review. No changes to criteria. Updated references

Topical Immunomodulators

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Prior Authorization Guideline

Guideline ID	GL-129249
Guideline Name	Topical Immunomodulators

Guideline Note:

Effective Date:	10/1/2023
P&T Approval Date:	6/19/2019
P&T Revision Date:	06/17/2020 ; 03/17/2021 ; 06/16/2021 ; 06/15/2022 ; 8/17/2023

1 . Indications

Drug Name: Elidel (pimecrolimus)
Mild to Moderate Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
Drug Name: Protopic (tacrolimus)
Moderate to Severe Atopic Dermatitis Indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.

2 . Criteria

Product Name: Brand Elidel cream, generic pimecrolimus cream, Brand Protopic ointment	
Approval Length	12 month(s)
Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), contraindication or intolerance of generic tacrolimus ointment</p>	

3 . References

1. Elidel Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. September 2020.
2. Protopic Prescribing Information. LEO Pharma Inc. Madison, NJ. June 2022.

4 . Revision History

Date	Notes
8/2/2023	Annual review, no changes to criteria

Topical Retinoid Agents

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Prior Authorization Guideline

Guideline ID	GL-127308
Guideline Name	Topical Retinoid Agents

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	12/16/2005
P&T Revision Date:	11/14/2019 ; 11/14/2019 ; 04/15/2020 ; 09/16/2020 ; 11/12/2020 ; 02/18/2021 ; 05/20/2021 ; 12/15/2021 ; 10/19/2022 ; 02/16/2023 ; 06/21/2023 ; 7/19/2023

1 . Indications

Drug Name: Atralin (tretinoin), Avita (tretinoin) cream and gel, Retin-A (tretinoin) cream and gel, Retin-A Micro (tretinoin) gel

Acne vulgaris Indicated for the topical treatment of acne vulgaris.

Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease wound healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.

Actinic keratosis [9]

Hyperkeratosis [9]

Keloid scar [9]

Drug Name: Akliel (trifarotene) cream, Arazlo (tazarotene) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Drug Name: Altreno (tretinoin) lotion

Acne vulgaris Indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Off Label Uses: Wound healing (mild) [9] Tretinoin 0.05% cream has been shown to decrease wound healing time in patients receiving electroepilation. Enhanced healing of epidermal wounds in patients undergoing dermabrasion when pretreated with tretinoin 0.05% cream has been reported. DRUGDEX Recommendation: Adult, Class IIb, Evidence favors efficacy.

Actinic keratosis [9]

Hyperkeratosis [9]

Keloid scar [9]

Drug Name: Differin (adapalene) cream/lotion/gel/solution/pads

Acne vulgaris Indicated for the topical treatment of acne vulgaris.

Drug Name: Tazorac (tazarotene) cream 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with acne vulgaris.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) cream 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis.

Drug Name: Tazorac (tazarotene) gel 0.1%

Acne Vulgaris Indicated for the topical treatment of patients with facial acne vulgaris of mild to moderate severity.

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Tazorac (tazarotene) gel 0.05%

Plaque Psoriasis Indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement.

Drug Name: Fabior (tazarotene) foam

Acne Vulgaris Indicated for the topical treatment of acne vulgaris in patients 12 years of age or older.

2 . Criteria

Product Name: Avita, Brand Retin A Micro (0.06%, 0.08%)	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient is 25 years of age or younger</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <ul style="list-style-type: none"> • Patient is older than 25 years of age • Diagnosis of acne vulgaris (i.e., acne) 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin , facial mottling) is a benefit exclusion. [A]

Product Name: Akliel, Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.1% 0.04%), Brand Adapalene 0.1% Soln, Brand Adapalene 0.1% Pads	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization

Approval Criteria

1 - One of the following:

1.1 Both of the following:

1.1.1 Patient is 25 years of age or younger

AND

1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

OR

1.2 All of the following:

1.2.1 Patient is older than 25 years of age

AND

1.2.2 Diagnosis of acne vulgaris (i.e., acne)

AND

1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:

- Adapalene (cream, gel)
- Topical tretinoin or tretinoin microsphere

Notes

Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Avita, Brand Retin A Micro (0.06%, 0.08%)

Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses: [A, 9]</p> <ul style="list-style-type: none"> • Actinic keratosis • Hyperkeratosis • Keloid scar • Wound healing (mild) 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Altreno, Atralin, Brand Retin-A, Brand Retin-A Micro (0.04%, 0.1%)	
Diagnosis	Other Medical Uses (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following diagnoses: [A, 9]</p> <ul style="list-style-type: none"> • Actinic keratosis • Hyperkeratosis • Keloid Scar • Wound healing (mild) <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to any generic topical tretinoin product</p>	

Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]
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Product Name: Brand Differin	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Patient is 25 years of age or younger</p> <p style="text-align: center;">AND</p> <p>1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:</p> <ul style="list-style-type: none"> • adapalene (cream, gel) • Topical tretinoin or tretinoin microsphere <p style="text-align: center;">OR</p> <p>1.2 All of the following:</p> <p>1.2.1 Patient is older than 25 years of age</p> <p style="text-align: center;">AND</p> <p>1.2.2 Diagnosis of acne vulgaris (i.e., acne)</p> <p style="text-align: center;">AND</p>	

<p>1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to BOTH of the following generics:</p> <ul style="list-style-type: none"> • adapalene (cream, gel) • Topical tretinoin or tretinoin microsphere 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Arazlo, Fabior, Brand Tazarotene 0.1% foam, Brand Tazorac 0.1% cream and gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Both of the following:</p> <p>1.1.1 Patient is 25 years of age or younger</p> <p style="text-align: center;">AND</p> <p>1.1.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:</p> <p>1.1.2.1 generic tazarotene</p> <p style="text-align: center;">AND</p> <p>1.1.2.2 One of the following:</p> <ul style="list-style-type: none"> • generic adapalene • generic topical tretinoin or tretinoin microsphere 	

OR	
1.2 All of the following:	
1.2.1 Patient is older than 25 years of age	
AND	
1.2.2 Diagnosis of acne vulgaris (i.e., acne)	
AND	
1.2.3 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication or intolerance to BOTH of the following:	
1.2.3.1 generic tazarotene	
AND	
1.2.3.2 One of the following:	
<ul style="list-style-type: none"> • generic adapalene • generic topical tretinoin or tretinoin microsphere 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Brand Tazorac	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
Approval Criteria	

<p>1 - Diagnosis of plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - Both of the following:</p> <p> 2.1 Trial and failure (of a minimum 30-day supply) within the past 180 days, or intolerance to generic tazarotene</p> <p style="text-align: center;">AND</p> <p> 2.2 Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)</p>	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel, generic tazarotene 0.05% gel	
Diagnosis	Plaque Psoriasis
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of plaque psoriasis</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply) within the past 180 days, contraindication, or intolerance to one medium to high potency topical corticosteroid (e.g., triamcinolone, fluocinonide)</p>	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

Product Name: Generic tazarotene 0.1% cream, generic tazarotene 0.1% gel	
Diagnosis	Acne Vulgaris
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - One of the following:</p> <p>1.1 Patient is 25 years of age or younger</p> <p style="text-align: center;">OR</p> <p>1.2 Both of the following:</p> <ul style="list-style-type: none"> • Patient is older than 25 years of age • Diagnosis of acne vulgaris (i.e., acne) 	
Notes	Treatment for cosmetic purposes (i.e., wrinkles, senile lentigo, solar elastosis, dyschromia, melasma or chloasma, hyperpigmentation of skin, facial mottling) is a benefit exclusion. [A]

3 . Background

Clinical Practice Guidelines	
<p>Table 1. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions) [10]</p>	
Uses	Medical vs. Cosmetic
Actinic keratosis	Medical
Alopecia areata	Medical
Chloasma	Cosmetic
Fine wrinkles on face	Cosmetic
Hyperkeratosis	Medical

Hyperpigmentation of skin, Facial mottling	Cosmetic
Keloid scar	Medical
Roughness of skin, Facial tactile roughness	Cosmetic
Systematized epidermal nevus	Medical
Ultraviolet-induced change in normal skin	Cosmetic
Wound healing (mild)	Medical

Table 2. Relative potencies of topical corticosteroids [14-15]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
Triamcinolone acetonide	Cream, ointment	0.5	
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025

	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

4 . Endnotes

- A. The use of topical retinoids for the following conditions was clarified as either medical or cosmetic (plan exclusions). [10] Please refer to Background section for table with details.

5 . References

1. Adapalene Topical Solution 0.1% Prescribing Information. Allegis Holdings LLC. Canton, MS. December 2020.
2. Aklied Prescribing Information. Galderma Laboratories, L.P. Fort Worth, Texas. January 2022.
3. Altreno Prescribing Information. Bausch Health US, LLC. Bridgewater, NJ. March 2020.
4. Atralin Prescribing Information. Valeant Pharmaceuticals. Bridgewater, NJ. July 2016.
5. Avita Prescribing Information. Mylan Pharmaceuticals Inc. Morgantown, WV. June 2018.
6. Differin Prescribing Information. Galderma Laboratories, L.P. Fort Worth, TX. June 2021.

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6 . Revision History

Date	Notes
6/29/2023	Removed generic adapalene cream, gel, and pump as targets from guideline.

Xalkori (crizotinib) - PA, NF



Prior Authorization Guideline

Guideline ID	GL-135284
Guideline Name	Xalkori (crizotinib) - PA, NF

Guideline Note:

Effective Date:	1/1/2024
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 ; 07/19/2023 ; 5/18/2023

1 . Indications

Drug Name: Xalkori (crizotinib)
<p>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.</p> <p>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.</p> <p>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.</p>

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
<p>Approval Criteria</p> <p>1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p> 2.1 Both of the following:</p> <p> 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)</p> <p style="text-align: center;">AND</p> <p> 2.1.2 One of the following:</p> <p> 2.1.2.1 Patient has had disease progression on, contraindication or intolerance to, or is not a candidate for one of the following:</p> <ul style="list-style-type: none"> • Alecensa (alectinib) • Alunbrig (brugatinib) <p style="text-align: center;">OR</p> <p> 2.1.2.2 For continuation of therapy</p>	

OR

2.2 Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)

Product Name: Xalkori	
Diagnosis	Anaplastic Large Cell Lymphoma (ALCL)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of systemic anaplastic large cell lymphoma (ALCL)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Relapsed • Refractory <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

Product Name: Xalkori	
Diagnosis	Inflammatory Myofibroblastic Tumor (IMT)
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Unresectable • Recurrent • Refractory <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

Product Name: Xalkori	
Diagnosis	All Indications
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

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

Product Name: Xalkori

Diagnosis	Non-small Cell Lung Cancer (NSCLC)
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Approval Length	12 month(s)
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Guideline Type	Non Formulary
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Approval Criteria

1 - Diagnosis of metastatic non-small cell lung cancer (NSCLC)

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 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 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 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)
Guideline Type	Non Formulary

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 - Submission of medical records (e.g., chart notes) confirming 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)
Guideline Type	Non Formulary
<p>Approval Criteria</p> <p>1 - Diagnosis of inflammatory myofibroblastic tumor (IMT)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is one of the following:</p> <ul style="list-style-type: none"> • Unresectable • Recurrent • Refractory <p style="text-align: center;">AND</p> <p>3 - Patient is 1 year of age or older</p> <p style="text-align: center;">AND</p> <p>4 - Submission of medical records (e.g., chart notes) confirming the patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA)</p>	

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
11/1/2023	Addition of drug specific NF criteria.

Xifaxan (rifaximin)



Prior Authorization Guideline

Guideline ID	GL-135073
Guideline Name	Xifaxan (rifaximin)

Guideline Note:

Effective Date:	1/1/2024
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1 . Indications

Drug Name: Xifaxan (rifaximin)
<p>Travelers' Diarrhea 200mg is indicated for the treatment of travelers' diarrhea (TD) caused by noninvasive strains of Escherichia coli in adults and pediatric patients 12 years of age and older. Limitations of use: Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than Escherichia coli. [A]</p> <p>Prophylaxis of Hepatic Encephalopathy Recurrence 550 mg is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. In the trials of Xifaxan for HE, 91% of patients were using lactulose concomitantly. Differences in the treatment effect of those patients not using lactulose concomitantly could not be assessed. Xifaxan has not been studied in patients with MELD (Model for End-Stage Liver Disease) score greater than 25, and only 8.6% of patients in the controlled trial had MELD scores over 19. There is increased systemic exposure in patients with more severe hepatic dysfunction.</p> <p>Irritable Bowel Syndrome with Diarrhea 550 mg is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.</p> <p>Off Label Uses: Treatment of Hepatic Encephalopathy Used for the treatment of hepatic encephalopathy. [4, 5, 22]</p> <p>Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) Has been used for the treatment of small intestinal bacterial overgrowth. [7, 8, 10, 13]</p>

2 . Criteria

Product Name: Xifaxan 200 mg tablets*	
Diagnosis	Travelers' Diarrhea (TD)
Approval Length	1 Time only
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of travelers' diarrhea (TD)</p> <p style="text-align: center;">AND</p> <p>2 - Disease is moderate to severe [D, 9]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following:</p> <p>3.1 Trial and failure of one of the following: [2, 3, D, E]</p> <ul style="list-style-type: none"> • Zithromax (azithromycin) • Cipro (ciprofloxacin) • Levaquin (levofloxacin) • Ofloxacin <p style="text-align: center;">OR</p> <p>3.2 Resistance, contraindication, or intolerance to all of the following antibiotics:</p> <ul style="list-style-type: none"> • Zithromax (azithromycin) • Cipro (ciprofloxacin) • Levaquin (levofloxacin) • Ofloxacin 	

Notes	NOTE: *If patient meets criteria above, please approve at GPI-14.
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Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO)</p> <p style="text-align: center;">AND</p> <p>2 - One of the following:</p> <p>2.1 Trial and failure of two of the following antibiotics: [5, 16-21]</p> <ul style="list-style-type: none"> • Neomycin • Augmentin (amoxicillin/clavulanic acid) • Cipro (ciprofloxacin) • Bactrim (trimethoprim-sulfamethoxazole) • Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline • Flagyl (metronidazole) • Keflex (cephalexin) <p style="text-align: center;">OR</p> <p>2.2 Resistance, contraindication, or intolerance to all of the following antibiotics:</p> <ul style="list-style-type: none"> • Neomycin • Augmentin (amoxicillin/clavulanic acid) • Cipro (ciprofloxacin) • Bactrim (trimethoprim-sulfamethoxazole) • Vibramycin (doxycycline) or Minocin (minocycline) or tetracycline • Flagyl (metronidazole) 	

- Keflex (cephalexin)

Product Name: Xifaxan	
Diagnosis	Small Bowel Bacterial Overgrowth (SBBO)/Small Intestinal Bacterial Overgrowth (SIBO) (off-label)
Approval Length	3 Months [C]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Patient demonstrates positive clinical response to therapy (e.g., resolution of symptoms or relapse with Xifaxan discontinuation) [B]</p>	

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) [F]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older [L]</p> <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to a Tricyclic Antidepressant (e.g., amitriptyline)</p>	

Notes	NOTE: *If patient meets criteria above, please approve at GPI-14.
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Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Irritable Bowel Syndrome with Diarrhea (IBS-D)
Approval Length	2 Weeks [1, I]
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Symptoms of Irritable Bowel Syndrome continue to persist [G, H]</p> <p style="text-align: center;">AND</p> <p>2 - Patient demonstrates positive clinical response to therapy as evidenced by both of the following: [1]</p> <ul style="list-style-type: none"> • Improvement in abdominal pain • Reduction in the Bristol Stool Scale <p style="text-align: center;">AND</p> <p>3 - Trial and failure, contraindication, or intolerance to a Tricyclic Antidepressant (e.g., amitriptyline)</p>	
Notes	NOTE: *If patient meets criteria above, please approve at GPI-14.

Product Name: Xifaxan 550 mg tablets*	
Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Initial Authorization
Guideline Type	Prior Authorization
<p>Approval Criteria</p>	

1 - Used for prophylaxis of hepatic encephalopathy (HE) recurrence

AND

2 - Patient is 18 years of age or older [L]

AND

3 - One of the following: [J, 22]

3.1 Both of the following:

3.1.1 Used as add-on therapy to lactulose

AND

3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy

OR

3.2 History of contraindication or intolerance to lactulose

Notes	NOTE: *If patient meets criteria above, please approve at GPI-14.
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Product Name: Xifaxan 550 mg tablets*

Diagnosis	Prophylaxis of Hepatic Encephalopathy (HE) Recurrence
Approval Length	12 month(s)
Therapy Stage	Reauthorization
Guideline Type	Prior Authorization

Approval Criteria

1 - Patient demonstrates positive clinical response to therapy [M, 27, 28]

Notes	NOTE: *If patient meets criteria above, please approve at GPI-14.
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Product Name: Xifaxan	
Diagnosis	Treatment of Hepatic Encephalopathy (Off-Label)
Approval Length	12 month(s)
Guideline Type	Prior Authorization
<p>Approval Criteria</p> <p>1 - Used for the treatment of hepatic encephalopathy (HE) [5, K]</p> <p style="text-align: center;">AND</p> <p>2 - Patient is 18 years of age or older [L]</p> <p style="text-align: center;">AND</p> <p>3 - One of the following: [22, K]</p> <p> 3.1 Both of the following:</p> <p> 3.1.1 Used as add-on therapy to lactulose</p> <p style="text-align: center;">AND</p> <p> 3.1.2 Patient is unable to achieve an optimal clinical response with lactulose monotherapy</p> <p style="text-align: center;">OR</p> <p> 3.2 History of contraindication or intolerance to lactulose</p>	

3 . Endnotes

- A. Antibiotic treatment should be avoided in diarrhea caused by enterohemorrhagic E. coli. [6]

- B. The main goals in the treatment of SBBO are 1) treatment of underlying small intestinal abnormality, when possible; 2) concentration on long-term antibiotic therapy when surgical management is not feasible; 3) adjunctive treatment of dysmotility, such as a prokinetic agent; and 4) nutritional support, particularly in patients with weight loss or vitamin deficiency. [7]
- C. In most patients, a single course of treatment (10 days) markedly improves symptoms, and patients may remain free of symptoms for months. In others, symptoms recur quickly, and acceptable results can only be obtained with cyclic treatment (1 of every 4 weeks). In still others, continuous treatment may be needed for 1 to 2 months. If the antimicrobial agent is effective, a resolution or marked diminution of symptoms will be notable within several days of initiating therapy. Diarrhea and steatorrhea will decrease, and cobalamin malabsorption will be corrected. [7]
- D. According to the Centers for Disease Control and Prevention's Yellow Book, antibiotics may be used to treat cases of moderate to severe travelers' diarrhea. Fluoroquinolones including, but not limited to, ciprofloxacin and levofloxacin, are considered first line agents in the treatment of Traveler's Diarrhea (TD). Azithromycin is also considered a first line agent for treatment of TD and is especially efficacious in the pediatric population. The overall usefulness of Rifaximin for empiric self-treatment remains to be determined as Rifaximin has only been shown to be efficacious in patients with noninvasive strains of *E. coli*. [9]
- E. Levofloxacin, ofloxacin and ciprofloxacin have all been shown to be highly effective in the treatment and prevention of Travelers' Diarrhea and should be considered first-line therapy options for this indication. [11]
- F. In the TARGET I, II and III pivotal trials, Irritable Bowel Syndrome was diagnosed using the ROME II diagnostic criteria. According to the ROME-II criteria, an IBS-D diagnosis requires at least 12 consecutive weeks in the previous 12 months of abdominal discomfort or pain that has two out of the three following features: relieved with defecation; and/or onset associated with a change in frequency of stool; and/or onset associated with a change in appearance of stool [12, 14]
- G. In the TARGET III pivotal trial, a total of 636 responders (59%) required retreatment. The median time to recurrence for patients who experienced initial response was 10 weeks (range from 6 to 24 weeks) [14]
- H. According to the ROME-IV criteria, recurrent signs and symptoms of IBS-D include the following: a return of abdominal pain or mushy/watery stool consistency for at least 3 weeks during a 4-week follow-up period. [15]
- I. The recommended dose of Xifaxan for IBS-D is one 550 mg tablet taken orally three times a day for 14 days. [1]
- J. The American Association for the Study of Liver Diseases (AASLD) and the European Association for the Study of the Liver (EASL) recommend rifaximin as an effective add-on therapy to lactulose for prevention of over hepatic encephalopathy with strength of recommendation 1A. No solid data support the use of rifaximin alone. [22]
- K. Rifaximin has been used for the treatment of HE in a number of trials comparing it with placebo, other antibiotics, nonabsorbable disaccharides, and in dose-ranging studies. These trials showed effect of rifaximin that was equivalent or superior to the compared agents with good tolerability. No solid data support the use of rifaximin alone. [22]
- L. A minimum age requirement that aligns with the prescribing information was added for prophylaxis and treatment of hepatic encephalopathy and IBS-D to prevent misuse of Xifaxan in pediatrics. The same age requirement was not added for traveler's diarrhea or SBBO/SIBO due to the patient population (e.g., pediatrics) that Xifaxan was studied in. [1, 8, 10, 13, 26]

- M. The risk of a breakthrough episode of hepatic encephalopathy (HE) in patients who recently had history of recurrent overt HE was reduced while taking Xifaxan. Additionally, patients on Xifaxan achieved full resolution of HE, so there is benefit with long-term use of Xifaxan for the prophylaxis of HE. [27, 28]

4 . References

1. Xifaxan prescribing information. Salix Pharmaceuticals, Inc. Bridgewater, NJ. October 2020.
2. DuPont HL, Jiang Z-D, Ericsson CD, et al. Rifaximin versus ciprofloxacin for the treatment of travelers' diarrhea: a randomized, double-blind clinical trial. *Clin Infect Dis*. 2001;33:1807-15.
3. Riddle MS, Connor BA, Beeching NJ, et al. Guidelines for the prevention and treatment of travelers' diarrhea: a graded expert panel report. *J Travel Med*. 2017;24(suppl 1):S63-S80.
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5 . Revision History

Date	Notes
10/17/2023	Program update to standard reauthorization language. No changes to clinical intent.

Xiidra (lifitegrast)

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Prior Authorization Guideline

Guideline ID	GL-137235
Guideline Name	Xiidra (lifitegrast)

Guideline Note:

Effective Date:	1/1/2024
P&T Approval Date:	8/18/2016
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 03/16/2022 ; 03/15/2023 ; 3/15/2023

1 . Indications

Drug Name: Xiidra (lifitegrast)
Dry eye disease Indicated for the treatment of the signs and symptoms of dry eye disease (DED).

2 . Criteria

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

Approval Criteria

1 - Diagnosis of dry eye disease

Product Name: Xiidra

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

1 - Patient demonstrates positive clinical response to therapy (e.g., increased tear production or improvement in dry eye symptoms)

3 . Endnotes

- A. As disease severity increases, aqueous enhancement of the eye using topical agents is appropriate (i.e., emulsions, gels, and ointments can be used). Topical cyclosporine, topical corticosteroids, topical lifitegrast, systemic omega-3 fatty acid supplements, punctual plugs and spectacle side shields/moisture chambers may also be considered in addition to aqueous enhancement therapies in patients who need additional symptom management. [2]

4 . References

1. Xiidra Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. July 2020.
2. American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Committee. Dry Eye Syndrome PPP - 2018. November 2018. <https://www.aao.org/preferred-practice-pattern/dry-eye-syndrome-ppp-2018>. Accessed January 28, 2022.

5 . Revision History

Date	Notes
12/1/2023	Program update to standard reauthorization language. No changes to clinical intent.

Xultophy (insulin degludec/ liraglutide)



Prior Authorization Guideline

Guideline ID	GL-126110
Guideline Name	Xultophy (insulin degludec/ liraglutide)

Guideline Note:

Effective Date:	8/1/2023
P&T Approval Date:	5/17/2017
P&T Revision Date:	04/15/2020 ; 06/17/2020 ; 06/16/2021 ; 06/15/2022 ; 6/21/2023

1 . Indications

Drug Name: Xultophy (insulin degludec/ liraglutide)
<p>Type 2 diabetes Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: XULTOPHY 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise because of the uncertain relevance of the rodent C-cell tumor findings to humans. XULTOPHY 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist. XULTOPHY 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. XULTOPHY 100/3.6 has not been studied in combination with prandial insulin.</p>

2 . Criteria

Product Name: Xultophy	
Approval Length	12 month(s)

Guideline Type	Step Therapy
<p>Approval Criteria</p> <p>1 - Requested drug is being used for a Food and Drug Administration (FDA)-approved indication</p> <p style="text-align: center;">AND</p> <p>2 - Trial and failure (of a minimum 30-day supply), contraindication, or intolerance to one metformin-containing agent</p>	

3 . References

1. Xultophy Prescribing Information. Novo Nordisk Inc. Bagsvaerd, Denmark. June 2022.

4 . Revision History

Date	Notes
6/12/2023	Annual review - added diagnosis statement and changed ST prerequisites to allow for any metformin-containing agent.