

## ACE INHIBITORS

**Drug Class:** ACE Inhibitors

**Preferred Agents:** *No Prior Authorization required*

benazepril/ benazepril HCT  
enalapril/ enalapril HCT  
enalapril solution (generic Epaned)  
lisinopril/ lisinopril HCT  
ramipril

**Preferred Agent Medication-specific criteria below:**

### ENALAPRIL SOLUTION

- Patient has difficulty swallowing.

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                            |                           |
|----------------------------|---------------------------|
| Accupril®                  | Monopril® / Monopril HCT® |
| Accuretic®                 | perindopril               |
| Altace®                    | Qbrelis®                  |
| captopril/ captopril HCT   | quinapril / quinapril HCT |
| Epaned®                    | trandolapril              |
| fosinopril/ fosinopril HCT | Vasotec® / Vaseretic®     |
| Lotensin®/ Lotensin HCT®   | Zestril® / Zestoretic®    |
| moexipril                  |                           |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable and switching would cause a deterioration in condition; **OR**
- Therapeutic failure on one preferred medication
- **See additional medication-specific criteria below:**

### EPANED® (ENALAPRIL SOLUTION)

- Patient has difficulty swallowing.

### QBRELIS®

- PDL criteria may be bypassed if patient is unable to swallow tablets.

**Duration of Approval:** 1 year

## ALPHA ADRENERGIC AGENTS

**Drug Class:** Alpha Adrenergic Agents

**Preferred Agents:** *No Prior Authorization required*

clonidine  
clonidine ER  
clonidine transdermal  
guanfacine  
methyldopa  
Nexiclon XR®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

methyldopa / HCTZ

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication

**Duration of Approval:** 1 year

## ALZHEIMER'S DEMENTIA

**Drug Class:** Alzheimer's Dementia

**Preferred Agents:** *No Prior Authorization required*

donepezil tabs, ODT  
Exelon® patch  
galantamine immediate release  
memantine immediate release  
rivastigmine capsules

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Adlarity®  
Aricept®  
donepezil 23 mg®  
galantamine ER caps, solution  
memantine ER  
Namenda®  
Namenda XR®  
Namzaric®  
rivastigmine patch  
Zunveyl

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## AMPYRA® / DALFAMPRIDINE

**Drug Class:** Multiple Sclerosis Agent – Potassium Channel Blocker

**FDA-approved uses:** Indicated as a treatment to improve walking in patients with multiple sclerosis (MS).

**Available dosage forms:** 10 mg Extended-Release Tablet

### **Coverage Criteria/Limitations for initial authorization**

- Diagnoses:** Documented diagnosis of multiple sclerosis with impaired walking ability
- Duration of Approval:**
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by a neurologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must not be wheelchair-bound
  - Patient must not have a history of seizures
  - Patient must not have moderate to severe renal impairment (Crcl < 50 ml/min)
  - Patient must be on disease modifying therapy for MS/confirmed diagnosis of MS
  - Documentation of significant and continuous walking impairment that impairs ability to complete normal activities of daily living (such as meal preparation, household chores, etc.) attributable to ambulation or functional status despite optimal treatment for Multiple Sclerosis
  - And, Baseline 25-ft walking test between 8 and 45 seconds

**OR**

  - Member is ambulatory\* **AND** has an Expanded Disability Status Scale (EDSS)\*\* score **greater than or equal to 4.5 but less than 7**  
*\*Does not require the use of a wheelchair (bilateral assistance is acceptable, such as a brace, cane, or crutch, as long as the patient can walk 20 meters without resting)*

*\*\*The Expanded Disability Status Score (EDSS) quantifies disability in eight functional systems: pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, cerebral, and other. EDSS scores 1.0 to 4.5 refer to people with multiple sclerosis who are fully ambulatory. EDSS scores 5.0 to 9.5 are defined by increasing impairment to ambulation.*
- Quantity:** 2 per day
- Age:** Patient is between 18 and 70 years old
- Route of Administration:** Oral

**Criteria for continuation of therapy**

**□ Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):

- Member currently meets ALL initial coverage criteria confirmed by documentation
- Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history
- Functional impairment resolved as a result of increased speed of ambulation resulting in the member being able to complete instrumental activities of daily living (such as meal preparation, household chores, etc.)

**AND**

- Improvement of at least 20% in timed walking speed as documented by the T25FW (timed 25-foot walk) from pre-treatment baseline:

**Contraindications/Exclusions/Discontinuation:**

- Patient does NOT have a diagnosis of spinal cord injury, myasthenia gravis, demyelinating peripheral neuropathies (such as Guillain-Barré syndrome), Alzheimer's disease, and Lambert Eaton myasthenic syndrome.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## AMYLIN ANALOGS

**Drug Class** Amylin Analogs

**Preferred Agents:** *No Prior Authorization required*

SymlinPen®

## ANDROGENIC AGENTS (TOPICAL)

**Drug Class:** Androgenic Agents (topical)

**Preferred Agents:** *Clinical Prior Authorization below*

testosterone gel pump (generic for Androgel)

**Clinical PA Criteria:**

- Serum testosterone levels <300 ng/dL
- For requests submitted for gender dysphoria
  - INITIAL REQUEST
    - Patient has had an initial evaluation completed by a health care provider experienced in gender dysphoria that specializes in treatment and evaluation of gender disorders (including health history, physical exam, desired treatment goals and relevant lab testing); **AND**
    - Persistent well documented gender dysphoria; **AND**
    - Patient has the ability to make a fully informed decision and consent of treatment; **AND**
    - Prior consent for treatment including potential adverse health effects, expected benefits/effects including future body image changes and potential effects on fertility; **AND**
    - No significant medical or mental health concerns and, if so, they been addressed and been deemed to not be a contraindication to therapy
  - RENEWAL REQUEST
    - Patient has had ongoing follow-up and monitoring following standard guidelines including addressing mental health concerns (for example, Version 7 WPATH Standards of Care or 2017 Clinical Practice Guideline, Endocrine Society <https://doi.org/10.1210/jc.2017-01658>)
- Contraindications:
  - Severe renal or cardiac diseases
  - Benign prostatic hyperplasia with obstruction
  - Prostate cancer
  - Undiagnosed genital bleeding
  - Breast cancer
  - Pregnancy

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Androgel® packet and gel pump

Fortesta®

Natesto

Testim®

testosterone

Vogelxo®

**Non-Preferred Agent PA Criteria:**

- Trial and failure with one preferred medication is required
- Decreased testosterone levels
- Contraindications:
  - Severe renal or cardiac diseases
  - Benign prostatic hyperplasia with obstruction
  - Prostate cancer
  - Undiagnosed genital bleeding
  - Breast cancer
  - Pregnancy

**Duration of Approval:** 1 year

## ANGIOTENSIN II-RECEPTOR NEPRILYSIN INHIBITORS (ARNIs)

**Drug Class:** Angiotensin II-Receptor Neprilysin Inhibitors (ARNIs)

**Preferred Agents:** *Clinical Prior Authorization below*

sacubitril-valsartan

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Entresto® Sprinkles

Entresto® Tablets

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication
- **See additional medication-specific criteria below:**

**ENTRESTO® (SACUBITRIL-VALSARTAN) SPRINKLES**

- Allow PDL bypass if patient is unable to swallow tablets

**Duration of Approval:** 1 year

## ANGIOTENSIN RECEPTOR ANTAGONISTS

**Drug Class:** Angiotensin Receptor Antagonists

**Preferred Agents:** *No Prior Authorization required*

irbesartan/ irbesartan HCT  
losartan/ losartan HCT  
olmesartan, olmesartan HCT  
valsartan/ valsartan HCT

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Arbli®  
Atacand® / Atacand HCT®  
Avapro®/ Avalide®  
Benicar®/ Benicar HCT®  
candesartan/ candesartan HCT  
Cozaar®  
Diovan®/ Diovan HCT®  
Edarbi®  
Edarbyclor®  
eprosartan  
Hyzaar®  
Micardis® / Micardis HCT®  
telmisartan/ telmisartan HCT

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Patient is clinically stable, and switching would cause a deterioration in condition; OR
- Therapeutic failure on one preferred medication
- See additional medication-specific criteria below:

**ARBli® ((losartan potassium))**

- Patient has difficulty swallowing; **AND**
- QL: 10ml per day

**Duration of Approval:** 1 year

## ANTICHOLINERGIC AGENTS – LONG ACTING

**Drug Class:** Anticholinergic Agents – Long Acting

**Preferred Agents:** *No Prior Authorization required*

Incruse Ellipta® (DPI)  
Spiriva® (DPI)  
Spiriva Respimat® (ISI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

tiotropium (DPI)  
Tudorza Pressair® (DPI)  
Yupelri® nebulizer solution

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

**Duration of Approval:** 1 year

## ANTICHOLINERGIC AGENTS – SHORT ACTING

**Drug Class:** Anticholinergic Agents – Short Acting

**Preferred Agents:** *No Prior Authorization required*

Atrovent HFA® (MDI)  
ipratropium nebulizer solution

**Non-Preferred Agents:** *Prior Authorization Criteria below*

ipratropium bromide (generic for Atrovent HFA®)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Patient is clinically stable, and switching would cause a deterioration in condition; OR
- Therapeutic failure on one preferred medication

**Duration of Approval:** 1 year

## ANTIBIOTICS – INHALED

**Preferred Agents:** *No Prior Authorization required*

Bethkis® ampule  
Cayston® inhalation solution  
Kitabis® pak  
Tobi-Podhaler®  
tobramycin solution (Generic for Tobi inhalation solution)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

TOBI inhalation solution  
tobramycin pak (Generic for Kitabis Pak)  
tobramycin ampule (Generic for Bethkis ampule)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one month with one preferred medication

**Duration of Approval:** 1 year

## ANTICOAGULANTS

**Drug Class:** Anticoagulants

**Preferred Agents:** *No Prior Authorization required*

dabigatran etexilate  
Eliquis®  
enoxaparin  
Jantoven®  
warfarin  
Xarelto®/ Xarelto® Dose Pack

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Arixtra®  
Eliquis (apixaban) tablets for oral suspension and sprinkle capsules  
fondaparinux  
Fragmin® syringes and vials  
Lovenox®  
Pradaxa®  
Pradaxa Oral Pellets®  
rivaroxaban  
Savaysa®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on one preferred medication
- **See additional medication-specific criteria below:**

**Eliquis® (apixaban)**

- Patient has difficulty swallowing; **AND**
- Quantity Limits: 1744 tablets for oral suspension per 102 days; 218 sprinkle capsules per 102 days

**PRADAXA ORAL PELLETS® (DAGABITRAN)**

- Patient must be ≤ 11 years old
- When used for VTE treatment, attestation that parenteral anticoagulation has been used for at least 5 days

- Duration of Approval:** Current prescription up to 6 months

## ANTIEMETICS

**D Drug Class:** Antiemetics

**Preferred Agents:** *No Prior Authorization required*

aprepitant 40mg, 80mg, 125mg capsules  
granisetron  
ondansetron 4mg, 8mg tablets, solution  
ondansetron ODT 4mg, 8mg

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Akynzeo®  
aprepitant 125-80-80mg pack  
Emend® 80mg capsules  
Emend Pack®  
ondansetron ODT 16mg  
Sancuso®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with 48-hour trial with one preferred medication
- **See additional medication-specific criteria below:**

**AKYNZEO**

- May only be approved for highly emetogenic regimens or regimens including anthracyclines and cyclophosphamide that are not considered highly emetogenic **and**
- Therapeutic failure on a preferred 5-HT3 receptor antagonist (granisetron, ondansetron) and a preferred substance P receptor agonist (Emend)

**QUANTITY LIMITS**

|  |  |
|--|--|
| Akynzeo® (netupitant/palonosetron)       | 1 per fill   |
| Emend® (aprepitant) tab                  | 125mg/80mg dose pack - 3 tablets per claim – billed by the tablet, not by the pack<br>40mg, 125mg tablet - 1 tablet per claim<br>80mg tablet - 2 tablets per claim |
| granisetron (Kytril®) 1mg tab            | 60 per 30 days   |
| granisetron (Kytril®) 1mg/5ml oral soln  | 150 mL per fill  |
| ondansetron (Zofran®)                    | ODT 4mg, 8mg Tablets – 60 per 30 days<br>ODT 16mg tablets – 30 per 30 days<br>4mg/5ml oral solution - 75mL per fill  |
| Sancuso® (granisetron) transdermal patch | 1 patch every 5 days   |

**Duration of Approval:** 1 year

## ANTIFUNGALS – ORAL

**Drug Class** : Antifungals – Oral

**Preferred Agents:** *No Prior Authorization required*

clotrimazole troches  
fluconazole  
griseofulvin oral suspension  
ketoconazole  
nystatin oral susp, tablets  
terbinafine

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                                 |                              |
|---------------------------------|------------------------------|
| Brexafemme®                     | Noxafil DR®                  |
| Cresemba®                       | Noxafil PowderMix Suspension |
| Diflucan®                       | Oravig®                      |
| flucytosine                     | posaconazole                 |
| griseofulvin tablet             | Sporanox®                    |
| griseofulvin microsize tablets  | Tolsura®                     |
| griseofulvin ultramicrosize tab | Vfend®                       |
| itraconazole                    | Vivjoa®                      |
| Noxafil®                        | voriconazole                 |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one month with one preferred medication; **OR**
- Serious illness resulting immunocompromised status
- **See additional medication-specific criteria below:**

**BREXAFEMME®**

- Diagnosis of vulvovaginal candidiasis; **OR**
- Patient has diagnosis of recurrent vulvovaginal candidiasis with  $\geq 3$  episodes of vulvovaginal candidiasis (VVC) in a 12-month period; **AND**
- Attestation that the provider has confirmed a negative pregnancy test or that the patient is not of childbearing potential
- Quantity Limit: Treatment = 4 tablets, Maintenance = 24 tablets
- Length of approval: Treatment = one time, Maintenance = 6 months

**CRESEMBA®**

- Diagnosis of aspergillosis; **OR**
- Diagnosis of mucormycosis; **AND**
- Patient is 6 years or older; **AND**
- Patient weight is >16 kg; **AND**
- Trial on voriconazole/Vfend or amphotericin B - approve without trials if intolerant to prerequisite meds or renal dysfunction

**NOXAFIL® (POSACONAZOLE) 300 MG SUSPENSION PACKETS**

- Maximum patient age = 17 years

**VFEND®**

- Aspergillosis – no trial/failure required

**SPORANOX®**

- Onychomycosis with previous failure on or contraindication to terbinafine: length of approval - toenails 12 weeks; fingernails - 6 weeks.
- Below diagnoses without previous trial:
  - Aspergillosis
  - Blastomycosis
  - Febrile neutropenia
  - Histoplasmosis

**VIVJOA®**

- Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period; **AND**
- Patient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); **AND**
- Patient has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole.
- Quantity limit: 18 tablets per treatment course
- Length of approval: one time

**QUANTITY LIMITS**

|   |   |
|---|---|
| Brexafemme® tablets                                 | Treatment = 4 tablets, Maintenance = 24 tablets                                 |
| fluconazole 150 mg tabs ( <i>Diflucan</i> ®)        | 4 per fill  |
| <i>terbinafine</i> ( <i>Lamisil</i> ®)              | 84 per fill   |
| Sporanox® ( <i>itraconazole</i> ) – brand & generic | 100 mg – 120 per 30 days<br>250 mg kit – 34 per fill<br>Solution – 840 per fill |
| <i>terbinafine</i> tabs ( <i>Lamisil</i> ®)         | 84 per fill   |
| Vivjoa® ( <i>oteseconazole</i> )                    | 18 per treatment course   |

- Duration of Approval:** For the duration of the prescription up to 6 months, unless otherwise noted in Medication-Specific Information

## ANTIFUNGALS – TOPICAL

**Drug Class:** Antifungals – Topical

**Preferred Agents:** *No Prior Authorization required unless noted*

ciclopirox 8% soln (generic Ciclodan®)  
ciclopirox 0.77% cream (generic for Loprox® and Ciclodan®)  
clotrimazole OTC cream, solution  
clotrimazole Rx cream  
clotrimazole/betamethasone cream  
econazole nitrate  
ketoconazole  
miconazole nitrate  
nystatin  
nystatin/triamcinolone cream, ointment  
tolnaftate cream, powder

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|   |                                  |
|---|----------------------------------|
| butenafine                                  | <b>Lasolex</b> ®                 |
| Ciclodan®                                   | Loprox®                          |
| ciclopirox suspension (generic for Loprox®) | Lotrimin AF®                     |
| ciclopirox gel, shampoo, kit                | miconazole/zinc oxide/petrolatum |
| clotrimazole / betamethasone lotion         | Micotrin AC®                     |
| clotrimazole RX solution                    | Mycozyl AC®                      |
| <b>econazole nitrate foam</b>               | Naftin®                          |
| Ertaczo®                                    | naftifine                        |
| Extina®                                     | oxiconazole                      |
| ketoconazole foam                           | Oxistat®                         |
| Ketodan®                                    | tavaborole                       |
|   | Vusion®                          |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with two weeks with two preferred medications; **OR**
- Organism resistant to the preferred medications
- **See additional medication-specific criteria below:**

**CICLOPIROX SHAMPOO**

- Bypass trial and failure of two preferred medications and instead allow a trial and failure of two weeks with one preferred shampoo medication

**ECONAZOLE NITRATE FOAM**

- Patient  $\geq$  12 years of age; **AND**
- Quantity Limit: 2.334 grams per day (~one 70gram tube per 30 day)

**TAVABOROLE**

- Diagnosis of toenail onychomycosis; and patient must be 6 years or older; and documented trial and failure on ciclopirox or allergy to ciclopirox (applies to brand and generic)

**VUSION® (*MICONAZOLE NITRATE/ZINC OXIDE/PETROLATUM*)**

- Maximum patient age = 16 years

**Duration of Approval:** For the duration of the prescription up to 6 months

## ANTI-HISTAMINES – 2<sup>ND</sup> GENERATION

**Drug Class:** Antihistamines – 2<sup>nd</sup> Generation

**Preferred Agents:** *No Prior Authorization required*

cetirizine tablets  
cetirizine 1mg/ml solution  
fexofenadine suspension  
fexofenadine tablets  
levocetirizine tablets  
loratadine / loratadine ODT

**Non-Preferred Agents:** *Prior Authorization Criteria below*

cetirizine chewable tabs, soft gels  
cetirizine 5mg/5ml solution (cups)  
Clarinet<sup>®</sup>  
desloratadine  
levocetirizine solution

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure on one preferred second-generation antihistamine or clinical rationale why they cannot be tried

**Duration of Approval:** 1 year

## ANTIHYPERTENSIVE COMBINATIONS: ACEI

**Drug Class:** Antihypertensive Combinations: ACEI

**Preferred Agents:** *No Prior Authorization required*

amlodipine / benazepril capsule

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Lotrel® capsule

trandolapril / verapamil tablet

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## ANTIHYPERTENSIVE COMBINATIONS: ARB

**Drug Class** : Antihypertensive Combinations: ARB

**Preferred Agents:** *No Prior Authorization required*

amlodipine/olmesartan  
amlodipine/valsartan  
amlodipine/valsartan/HCTZ

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Azor®  
amlodipine/olmesartan/HCTZ  
Exforge® / Exforge HCT®  
telmisartan/amlodipine  
Tribenzor®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## ANTIHYPERURICEMIC AGENTS

**Drug Class :** Antihyperuricemic Agents

**Preferred Agents:** *No Prior Authorization required*

allopurinol tablet  
colchicine tablets (generic for Colcris)  
febuxostat tablet  
probenecid/colchicine tablet  
probenecid tablet

**Non-Preferred Agents:** *Prior Authorization Criteria below*

colchicine capsules (generic for Mitigare)  
Colcris (colchicine) tablet  
Mitigare® (colchicine) capsules  
Uloric (febuxostat) tablet  
Zyloprim (allopurinol) tablet  
Gloperba (colchicine) Oral Solution

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of one preferred agent
- **See additional medication-specific criteria below:**

**COLCRYS® (COLCHICINE) TABLETS**

- PDL criteria may be bypassed for diagnosis of treatment of an acute gout flare or Familial Mediterranean Fever prophylaxis.

**GLOPERBA® (COLCHICINE) ORAL SOLUTION**

- Patient has difficulty swallowing tablets or has an enteral tube feeding

**Duration of Approval:** 1 year

## ANTIMIGRAINE AGENTS, ACUTE TREATMENT - TRIPTANS

**Drug Class:** Antimigraine Agents, Acute Treatment - Triptans

**Preferred Agents:** *No Prior Authorization required*

rizatriptan tab and ODT  
sumatriptan tablets, injection, nasal spray

**Non-Preferred Agents:** *Prior Authorization Criteria below*

almotriptan  
eletriptan  
Frova®  
frovatriptan  
Imitrex®  
naratriptan  
Maxalt®/ Maxalt MLT®  
Relpax®  
sumatriptan-naproxen  
**Symbravo (rizatriptan/meloxicam) tablet**  
Tosymra®  
Zembrace Symtouch®  
zolmitriptan, zolmitriptan ODT  
zolmitriptan nasal spray  
Zomig® nasal spray  
Zomig® tablet/ Zomig ZMT®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with treatment with use of two of the preferred agents

**QUANTITY LIMITS**

|   |   |
|---|---|
| almotriptan (Axert)                     | 9 per fill  |
| Frova® (frovatriptan)                   | 18 per fill   |
| Imitrex® (sumatriptan)                  | 18 per fill   |
| Imitrex Injection® (sumatriptan)        | Vial – 2 per fill<br>Kit and Injection – 4 per fill |
| Maxalt®/ Maxalt MLT® (rizatriptan)      | 18 per fill   |
| naratriptan (Amerge®)                   | 9 per fill  |
| Relpax® (eletriptan)                    | 12 per fill   |
| rizatriptan (Maxalt®/ Maxalt MLT®)      | 18 per fill   |
| sumatriptan (Imitrex®)                  | 18 per fill   |
| sumatriptan Injection (Imitrex®)        | Vial – 2 per fill<br>Injection – 4 per fill         |
| sumatriptan Spray, Nasal ( Tosymra®)    | 6 per fill  |
| Symbravo (rizatriptan/meloxicam) tablet | 1 bottle or 9 tablets per fill                      |
| zolmitriptan (Zomig®/ Zomig ZMT®)       | 12 per fill   |
| Zomig®/Zomig ZMT® (zolmitriptan)        | 12 per fill   |

**Duration of Approval:** 6 months

## ANTIMIGRAINE AGENTS, ACUTE TREATMENT - OTHER

**Drug Class:** Antimigraine Agents, Acute Treatment - Other

**Preferred Agents for Acute Migraines:** *Clinical Prior Authorization below*

Nurtec ODT®  
Ubrelvy®

**Clinical PA Criteria for Acute Migraines:**

- Patient has a diagnosis of migraine with or without aura; **AND**
- Patient is ≥18 years of age; **AND**
- Patient must have tried and failed, or have contraindication to one preferred triptan medication

**NURTEC ODT® (RIMEGEPANT)** – Quantity Limit: 54 tablets per 90 days

**UBRELVY® (UBROGEPANT)** – Quantity Limit: 16 tablets per 30 days

**Non-Preferred Agents for Acute Migraines:** *Prior Authorization Criteria below*

Brekiya®  
Elyxyb®  
Reyvow®  
Zavzpret®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of the preferred medication

**ELYXYB® (CELECOXIB)** – Quantity Limit: 14 doses (67.2 ml) per 30 days

**REYVOW® (LASMIDITAN)** – Quantity Limit: 8 tablets per 30 days

**ZAVZPRET® (ZAVEGEPANT)** – Quantity Limit: 8 nasal spray devices per 30 days

**BREKIYA® (dihydroergotamine mesylate)** – Quantity Limit: 8 ml (1 MG/ML Autoinjector) per 30 days

**Duration of Approval:** 1 year

## ANTIMIGRAINE AGENTS, PREVENTIVE TREATMENT

**Drug Class:** Antimigraine Agents, Preventive Treatment

**Preferred Agents for Migraine Prevention:** *Clinical Prior Authorization below*

Aimovig®  
Ajovy®  
Emgality®  
Nurtec ODT®  
Qulipta®

**Clinical PA Criteria for Migraine Prevention:**

- For initial requests:
  - Patient has a diagnosis of migraine with or without aura; **AND**
  - Patient is ≥ 18 years of age; **OR**
  - Patient age is 6 to 17 years and patient weighs at least 45 kg (Ajovy only); **AND**
  - Patient has ≥ four migraine days per month for at least three months; **AND**
  - Patient has tried and failed ≥ one-month trial of any two of the following oral medications:
    - Antidepressants (e.g., amitriptyline, venlafaxine)
    - Beta blockers (e.g., propranolol, metoprolol, timolol, atenolol)
    - Anti-epileptics (e.g., valproate, topiramate)
    - Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g., lisinopril, candesartan); **OR**
  - Diagnosis of cluster headaches (Emgality only)
- For Renewal requests:
  - Patient demonstrated significant decrease in the number, frequency, and/or intensity of headaches

**Non-Preferred Agents for Migraine Prevention:** *Prior Authorization Criteria below*

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**QUANTITY LIMITS**

|  |                        |
|--|------------------------|
| Emgality® (galcanezumab-gnlm) 120 mg/mL Pen, Syringe           | 3 mL per 90 days       |
| Emgality 300 mg Dose (3 x 100 mg/mL syringes)                  | 9 mL per 90 days       |
| Aimovig® (erenumab-aooe) 140 mg/mL Autoinjector                | 3 mL per 90 days       |
| Aimovig® (erenumab-aooe) 70 mg/mL Autoinjector                 | 6 mL per 90 days       |
| Nurtec® ODT (rimegepant) 75mg Tablet                           | 54 tablets per 90 days |
| Ajovy® (fremanezumab-vfrm) 225 mg/1.5 mL Autoinjector, Syringe | 4.5 mL per 90 days     |
| Qulipta® (atogepant) tablets                                   | 90 tablets per 90 days |

*An override will be approved for requests which demonstrate that prescribed loading dose will exceed the maintenance quantity limit in table above.*

**Duration of Approval:** 6 months; Renewal = 12 months

## ANTI-OBESITY/WEIGHT LOSS AGENTS

**Drug Class:** Anti-Obesity/Weight Loss Agents

**Preferred Agents (Non-GLP1s only):** *Clinical Prior Authorization below*

benzphetamine (only available as generic); C-III

diethylpropion (only available as generic); C-IV

*orlistat products:*

orlistat

Xenical (orlistat)

phendimetrazine (only available as generic); C-III

*phentermine products:*

Adipex-P (phentermine); C-IV

Lomaira (phentermine); C-IV

phentermine; C-IV

phentermine/topiramate (only available as generic); C-IV

### **Preferred Agent (Non-GLP1s only) Clinical PA Criteria:**

#### **Initial**

- Prescriber attests that the patient will **not** use more than one weight loss medication in this drug class concurrently; **AND**
- Patient  $\geq 18$  years of age; **OR**
- Patient age  $\geq 12$  years (Xenical/orlistat, phentermine/topiramate); **OR**
- Patient age  $\geq 17$  years (phentermine); **AND**
- Patient age  $\geq 12$  years to  $<18$  years must have an initial BMI per CDC growth charts at the 95<sup>th</sup> percentile or greater for age and sex (obesity); **OR**
- Patient age  $\geq 12$  years to  $<18$  years with BMI in the 85<sup>th</sup> – 94<sup>th</sup> percentile (overweight) per CDC growth charts **and** has at least one of the following weight-related coexisting conditions:
  - diabetes;
  - sleep apnea;
  - hypertension; or
  - dyslipidemia; **OR**
- Patient age  $\geq 18$  years (benzphetamine, diethylpropion, phendimetrazine); **AND**
- Patient age  $\geq 18$  years must have an initial body mass index [BMI]  $\geq$  than 30 kg/m<sup>2</sup>; **OR**
- Patient age  $\geq 18$  years must have an initial body mass index [BMI]  $\geq$  than 27 kg/m<sup>2</sup> but  $<30$  kg/m<sup>2</sup> **and** at least one of the following risk factors:
  - hypertension;
  - coronary artery disease;
  - diabetes;
  - dyslipidemia; or
  - sleep apnea; **AND**

- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

#### **Renewal**

- For patients age ≥12 years to <18 years, prescriber provides clinical documentation demonstrating BMI associated with the renewal request and showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy.
- For patients age ≥18 years, prescriber provides clinical documentation demonstrating weight associated with the renewal request and showing that the patient has maintained a weight loss of ≥ 5% from baseline weight at initiation of therapy.

#### **Non-Preferred (GLP1s only) Agents: *Prior Authorization Criteria below***

liraglutide (generic for Saxenda) [GLP1]

Saxenda® (liraglutide) [GLP1]

Wegovy (semaglutide) [GLP1]

Wegovy HD (semaglutide) [GLP1]

Zepbound® (tirzepatide) [GLP1]

#### **Non-Preferred (GLP1s only) PA Criteria:**

- Allergy to all five types of preferred medications (e.g., at least 1 of each benzphetamine, diethylpropion, orlistat products, phendimetrazine, and phentermine products); **OR**
- Contraindication or drug to drug interaction with all five types of preferred medications; **OR**
- History of unacceptable side effects of all five types of preferred medications; **OR**
- Trial and failure with all five types of preferred agents (e.g., at least one orlistat agent and one phentermine product in addition to benzphetamine, diethylpropion and phendimetrazine); **AND**
- *See additional clinical PA criteria below:*
- Prescriber attests that the patient will **not** use more than one weight loss medication in this drug class concurrently; **AND**
- Prescriber attests there has been documented failure of all other clinically appropriate weight loss interventions; **AND**

- Prescriber attests that use of this GLP1 agent for weight loss is considered only as a measure to avert the need for higher-cost bariatric surgery; **AND**
- Prescriber attests that the patient will not use an anti-obesity GLP-1 agonist (Wegovy, Saxenda/liraglutide or Zepbound) concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin); **AND**
- Patient  $\geq 18$  years of age (Wegovy HD, Zepbound); **OR**
- Patient age  $\geq 12$  years (Wegovy, Saxenda/liraglutide); **AND**
- Prescriber attests patient age  $\geq 12$  years to  $< 18$  years and has an initial BMI per CDC growth charts for age and sex and is classified as morbidly obese; **OR**
- Prescriber attests patient age  $\geq 18$  years and has an initial body mass index (BMI) classified as morbidly obese (e.g., baseline BMI  $\geq 40$  kg/m<sup>2</sup> or greater); **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

#### **Renewal**

- For patients age  $\geq 12$  years to  $< 18$  years, prescriber provides clinical documentation demonstrating BMI associated with the renewal request and showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy.
- For patients age  $\geq 18$  years, prescriber provides clinical documentation demonstrating weight associated with the renewal request and showing that the patient has maintained a weight loss of  $\geq 5\%$  from baseline weight at initiation of therapy.

#### **1<sup>st</sup> Renewal Request – For Weight Loss ONLY – in Established Members with Initial Approval Prior to 1/1/2026 Criteria Changes**

- Prescriber attests that the patient was classified as morbidly obese when they were initially started on the GLP1 agent for weight loss; **AND**
- Prescriber attests there was documented failure of all other clinically appropriate weight loss interventions prior to starting the GLP1 agent for weight loss; **AND**
- Prescriber attests that use of the GLP1 agent for weight loss was considered only as a measure to avert the need for higher-cost bariatric surgery; **AND**

- For patients age  $\geq 12$  years and  $< 18$  years, prescriber provides clinical documentation demonstrating BMI associated with the renewal request and showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy; **OR**
- For patients age  $\geq 18$  years, prescriber provides clinical documentation demonstrating the weight associated with the renewal request and showing that the patient has maintained a weight loss of  $\geq 5\%$  from baseline weight at initiation of therapy.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

**QUANTITY LIMITS**

|   |                                 |
|---|---------------------------------|
| Saxenda/liraglutide 18 mg/3 mL pens             | 15 mL (5 pens) per 30 days      |
| Wegovy (semaglutide) 0.25 mg/0.5 mL pens        | 2 mL (4 pens) per 28 days       |
| Wegovy (semaglutide) 0.50 mg/0.5 mL pens        | 2 mL (4 pens) per 28 days       |
| Wegovy (semaglutide) 1 mg/0.5 mL pens           | 2 mL (4 pens) per 28 days       |
| Wegovy (semaglutide) 1.7 mg/0.75 mL pens        | 3 mL (4 pens) per 28 days       |
| Wegovy (semaglutide) 2.4 mg/0.75 mL pens        | 3 mL (4 pens) per 28 days       |
| Wegovy HD (semaglutide) 7.2 mg/0.75 mL pen      | 3 mL per 28 days                |
| Xenical (orlistat) 120 mg capsules              | 90 caps per 30 days             |
| Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials   | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials  | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 12.5 mg/0.5 mL pens      | 2 mL (4 pens) per 28 days       |
| Zepbound (tirzepatide) 15 mg/0.5 mL pens        | 2 mL (4 pens) per 28 days       |
| ZEPBOUND 2.5MG/DOS(10MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 5MG/DOSE (20MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 7.5MG/DOS(30MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 10MG/DOSE(40MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 12.5MG/DOS(50MG/2.4ML)                 | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 15MG/DOSE(60MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |

**Duration of Approval:** Initial = 6 months, Renewal = 6 months

## ANTIPARKINSON'S AGENTS – DOPAMINE AGONISTS

**Drug Class:** AntiParkinson's Agents – Dopamine Agonists

**Preferred Agents:** *No Prior Authorization required*

pramipexole  
ropinirole

**Non-Preferred Agents:** *Prior Authorization Criteria below*

bromocriptine  
Mirapex ER®  
Neupro®  
**Onago (apomorphine) cartridge**  
Parlodel®  
pramipexole ER  
ropinirole ER

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication; **OR**
- Patients using bromocriptine for indications other than Parkinson's do not need to meet non-preferred agent criteria
- **See additional medication-specific criteria below:**

**NEUPRO® (ROTIGOTINE)**

- Quantity Limit (all strengths): 30 patches per 30 days

**Onago (apomorphine) cartridge**

- Patient is  $\geq 18$  years of age; **AND**
- Diagnosis of Parkinson's disease that is levodopa-responsive; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Prescriber attests that the patient is experiencing persistent motor fluctuations with a minimum of 3 hours of "off" time per day despite optimized carbidopa/levodopa therapy
- Quantity Limit: 30 cartridges/30days

**Duration of Approval:** 1 year

## ANTI-PARKINSON'S AGENTS – OTHER

**Drug Class:** AntiParkinson's Agents – Other

**Preferred Agents:** *No Prior Authorization required (except rasagiline)*

|                                 |                                     |
|---------------------------------|-------------------------------------|
| amantadine capsule, syrup       | entacapone                          |
| benztropine tablet (*Carve Out) | rasagiline                          |
| carbidopa tablet / levodopa ER  | trihexyphenidyl tablet (*Carve Out) |
| carbidopa/levodopa IR tablets   |                                     |

### **RASAGILINE (AZILECT®)**

- Patient is ≥ 18 years of age

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|  |                                     |
|--|-------------------------------------|
| amantadine tablet                          | Inbrija®                            |
| Azilect®                                   | Nourianz®                           |
| carbidopa                                  | Ongentys®                           |
| carbidopa tablet / levodopa ODT            | Rytary ER®                          |
| carbidopa-levodopa ER (generic for Rytary) | selegiline capsule, tablet          |
| carbidopa/levodopa/entacapone tablet       | Sinemet®                            |
| Crexont®                                   | tolcapone                           |
| Dhivy®                                     | trihexyphenidyl elixir (*Carve Out) |
| Duopa®                                     | Vyalev®                             |
| Gocovri®                                   | Xadago®                             |

### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication
- **See additional medication-specific criteria below:**

### **AZILECT® (RASAGILINE)**

- Patient is ≥ 18 years of age

### **CREXONT® (CARBIDOPA/LEVODOPA)**

- Patient is 18 years or older; **AND**
- Prescribed by or in consultation with a neurologist

### **GOCOVRI® (AMANTADINE EXTENDED-RELEASE)**

- Diagnosis of dyskinesia associated with Parkinson’s disease; **OR**
- Experiencing Off-episodes of Parkinson’s disease; **AND**
- The patient is receiving concomitant levodopa-based therapy; **AND**
- Patient has failure, contraindication or intolerance to immediate-release amantadine

**INBRIJA® (LEVODOPA INHALATION)**

- Prescribed by or in consultation with a neurologist; **AND**
- Medication will be used concomitantly with levodopa/carbidopa

**ONGENTYS® (OPICAPONE)**

- Patient has a diagnosis of Parkinson’s Disease; **AND**
- Patient is experiencing ‘off’ time on levodopa/carbidopa therapy; **AND**
- Medication will be used concomitantly with levodopa/carbidopa and will not be used as monotherapy.

**RYTARY ER® (CARBIDOPA/LEVODOPA ER)**

- Patient is 18 years of age or older **AND**
- Prescribed by or in consultation with a neurologist

**VYALEV® (FOSLEVODOPA AND FOSCARBIDOPA)**

- Patient is 18 years of age or older; **AND**
- Diagnosis of Parkinson’s disease that is levodopa-responsive; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Prescriber attests that the patient is experiencing persistent motor fluctuations with a minimum of 2.5 hours of “off” time per day despite optimized carbidopa/levodopa therapy

**XADAGO® (SAFINAMIDE)**

- Patient must be 18 years or older
- Patient is experiencing ‘off’ time on levodopa/carbidopa therapy; **AND**
- Medication will be used concomitantly with levodopa/carbidopa and will not be used as monotherapy.

**Duration of Approval:** Up to 1 year

\*Carved Out- Bill Fee-For-Service Medicaid  
(See MPPL @ <https://mi.primetherapeutics.com> for coverage details)

## ANTIPSORIATIC - TOPICAL VITAMIN D ANALOGS

**Drug Class:** Dermatological – Antipsoriatics

**FDA-approved uses:** Indicated for the topical treatment of psoriasis

**Available dosage forms:**

- Calcipotriene 0.005% Cream, Ointment and Solution
- Calcitriol 3 mcg/g ointment

**Coverage Criteria/Limitations for initial authorization**

- Diagnoses:** Psoriasis
- Duration of Approval**
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 12 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Prescribed to treat an FDA approved indication for Topical Vitamin D analogs; **AND**
  - Documented trial, failure, or intolerance of at least one high potency or very high potency topical steroid; **OR**
  - Documented trial, failure, or intolerance of one low or medium potency topical steroid and justification for avoidance of a higher potency topical steroid; **OR**
  - Topical steroid avoidance due to pediatric age
- Quantity:** Appropriate amount to cover affected area for up to 34 days based on provider estimate or body surface area (BSA) estimate.
  - Topical calcipotriene limits are as follows. Prescriber must provide clinical justification for exceeding safe limit.
    - Adults – max recommended is 100 grams/week
    - Children ≥ 2 years – max recommended is 50 grams/week
  - Topical calcitriol ointment limits are as follows. Prescriber must provide clinical justification for exceeding safe limit.
    - Adults – max recommended is 200 grams/week
    - Children ≥ 2 years to < 7 years – max recommended is 100 grams/week
    - Children ≥ 7 years – max recommended is 200 grams/week
- Age:** ≥ 2 years old
- Route of Administration:** Topical

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Attestation that topical calcipotriene or calcitriol has contributed to a positive response or patient is stable on therapy.

**Contraindications/Exclusions/Discontinuation:**

- Therapy may be discontinued if patient is noncompliant with therapy **OR** no demonstrable clinically significant improvement in condition has occurred within 6 months of therapy initiation.

## ANTIVIRALS – COVID-19

**Drug Class** Antivirals – COVID-19

**Preferred Agents:** *No Prior Authorization required*

Paxlovid®

## ANTIVIRALS – HERPES

**Drug Class:** Antivirals – Herpes

**Preferred Agents:** *No Prior Authorization required*

acyclovir tablets, capsules, suspension  
famciclovir  
valacyclovir

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Valtrex®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure on ten days of two preferred medications

**Duration of Approval:** For the duration of the prescription up to 6 months

## ANTIVIRALS – INFLUENZA

**Drug Class:** Antivirals – Influenza

**Preferred Agents:** *No Prior Authorization required*

oseltamivir  
Relenza®  
rimantadine

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Flumadine®  
Tamiflu®  
Xofluza®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a five-day trial with two preferred medications

**QUANTITY LIMITS**

|  |   |
|--|---|
| Tamiflu® and solution ( <i>oseltamivir</i> ) – brand & generic | Capsules – 14 per fill<br>12 mg/mL solution – 50 mL per fill<br>6 mg/mL – 120 mL per fill |
|--|---|

**Duration of Approval:** For the duration of the prescription up to 6 months

## ANTIVIRALS – TOPICAL

**Drug Class:** Antivirals – Topical

**Preferred Agents:** *No Prior Authorization required*

acyclovir cream  
acyclovir ointment  
Denavir®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

penciclovir (generic for Denavir)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

**Duration of Approval:** 1 year

# AUSTEDO/ DEUTETRABENAZINE

**Drug Class** Movement Disorder Therapy - Tardive Dyskinesia, Huntington's Disease

**FDA-approved uses:** Tardive Dyskinesia, Chorea associated with Huntington's

**Available dosage forms:** Tablets: 6mg, 9mg, 12mg, XR 6mg, Titration XR (12-18-24-30), XR 12mg, XR 18mg, XR 24mg, XR 30mg, XR 36mg, XR 42mg, XR 48mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Diagnosis of chorea associated with Huntington's disease; **OR**
  - Diagnosis of tardive dyskinesia secondary to current or past use of a dopamine antagonist (e.g., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by or in consultation with a neurologist or psychiatrist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - For tardive dyskinesia attestation that a baseline AIMS test has been completed
- Age:** Patient is 18 years of age or older

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Attestation of patient's improvement in symptoms associated with their condition; **AND**
  - For tardive dyskinesia, attestation that a follow-up AIMS test has been completed and there has been a positive response to therapy

**QUANTITY LIMITS**

|   |                         |
|---|-------------------------|
| Austedo IR 6mg tablets  | 240 tablets per 30 days |
| Austedo IR 9mg tablets  | 150 tablets per 30 days |
| Austedo IR 12mg tablets   | 120 tablets per 30 days |
| Austedo XR tablets (6mg, 12mg, 18mg, 24mg, 30mg 36mg, 42mg, 48mg)   | 30 tablets per 30 days  |
| Austedo XR Titration pack (12-18-24-30mg); 4-week blister package contains 7x 12mg tablets, 7x 18mg tablets, 7x 24mg tablets, and 7x 30mg tablets | 28 tablets per 365 days |

## BENZNIDAZOLE

**Drug Class:** Anti-Inflammatory Tumor Necrosis Factor Inhibiting Agents, TNF=alpha set

**Background:**

- Benznidazole, a nitroimidazole antimicrobial, is indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi*.<sup>1</sup>  
Antiparasitic treatment is indicated for all cases of acute or reactivated Chagas disease and for chronic *Trypanosoma cruzi* (*T. cruzi*) infection in children up to 18 years old. Congenital infections are considered acute disease. Treatment is strongly recommended for adults up to 50 years old with chronic infection who do not already have advanced Chagas cardiomyopathy. For adults older than 50 years with chronic *T. cruzi* infection, the decision to treat with antiparasitic drugs should be individualized, weighing the potential benefits and risks for the patient. Physicians should consider factors such as the patient's age, clinical status, preference, and overall health.<sup>2</sup>

**Authorization:**

- Diagnosis of Chagas disease (American trypanosomiasis) due to *Trypanosoma cruzi*
- Authorization will be issued for 60 days.

**References:**

- Benznidazole [prescribing information]. Laboratorios Liconsa S.A., Guadalajara, Spain. August 2017.
- CDC Guidelines. Parasites – American Trypanosomiasis (also known as Chagas Disease). <https://www.cdc.gov/parasites/chagas/>. December 2017.

## BETA ADRENERGIC AND ANTICHOLINERGIC COMBINATIONS

**Drug Class:** Beta Adrenergic and Anticholinergic Combinations

**Preferred Agents:** *No Prior Authorization required*

Anoro Ellipta® (DPI)  
Bevespi Aerosphere® (MDI)  
Combivent RESPIMAT® (ISI)  
ipratropium/albuterol nebulizer solution  
Stiolto Respimat® (ISI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Duaklir Pressair® (DPI)  
umeclidinium/vilanterol (DPI)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

**Duration of Approval:** 1 year

## BETA ADRENERGIC AND CORTICOSTEROID INHALER COMBINATIONS

**Drug Class:** Beta Adrenergic and Corticosteroid Inhaler Combinations

**Preferred Agents:** *No Prior Authorization required*

Advair Diskus® (DPI)  
 Advair HFA® (MDI)  
 Dulera® (MDI)  
 Symbicort® (MDI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

AirDuo Digihaler  
 AirDuo Respiclick® (DPI)  
 Breo Ellipta® (DPI)  
 Breyna®  
 budesonide/formoterol (generic for Symbicort)  
 fluticasone/vilanterol (generic for Breo Ellipta)  
 fluticasone/salmeterol (generic for Advair Diskus)  
 fluticasone/salmeterol (generic for Advair HFA)  
 fluticasone/salmeterol (generic for AirDuo)  
 Wixela® (DPI) (generic for Advair Diskus)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

|  |                        |
|--|------------------------|
| Advair Diskus (fluticasone/salmeterol)     | 3 inhalers per 90 days |
| Advair HFA (fluticasone/salmeterol)        | 3 inhalers per 90 days |
| Airduo Respiclick (fluticasone/salmeterol) | 3 inhalers per 90 days |
| Airduo Digihaler(fluticasone/salmeterol)   | 3 inhalers per 90 days |
| Breo Ellipta (fluticasone/vilanterol)      | 3 inhalers per 90 days |
| Breyna (budesonide/formoterol)             | 6 inhalers per 90 days |
| Dulera (mometasone/formoterol)             | 3 inhalers per 90 days |
| Symbicort (budesonide/formoterol)          | 6 inhalers per 90 days |
| Wixela (fluticasone/salmeterol)            | 3 inhalers per 90 days |

### MAXIMUM AGE LIMITS

|   |          |
|---|----------|
| Breo Ellipta (fluticasone/vilanterol) 50-25 mcg | 11 years |
| Dulera (mometasone/formoterol) 50 mcg/5mcg      | 11 years |

**Duration of Approval:** 1 year

## **BETA ADRENERGIC / ANTICHOLINERGIC / CORTICOSTEROID INHALER COMBINATIONS**

**Drug Class:** Beta Adrenergic / Anticholinergic Combinations / Corticosteroid Inhalers Combinations

**Preferred Agents:** *No Prior Authorization required*

Trelegy Ellipta

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Breztri Aerosphere

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition; **OR**
- Therapeutic failure after a two-week trial with the preferred medication

**Duration of Approval:** 1 year

## BETA ADRENERGICS – LONG ACTING

**Drug Class:** Beta Adrenergics – Long Acting

**Preferred Agents:** *No Prior Authorization required*

Serevent® (DPI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

arformoterol nebulizer solution  
Brovana® nebulizer solution  
formoterol nebulizer solution  
Perforomist® nebulizer solution  
Striverdi Respimat® (ISI)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication
- **See additional medication-specific criteria below:**

**BROVANA® (ARFORMOTEROL) NEBULIZER SOLUTION**

- Bypass PDL criteria if patient requires long-acting beta-adrenergic medication and cannot use a dry powder inhaler

**PERFOROMIST® (FORMOTEROL) NEBULIZER SOLUTION**

- Bypass PDL criteria if patient requires long-acting beta-adrenergic medication and cannot use a dry powder inhaler

**STRIVERDI RESPIMAT® (OLODATEROL) INHALER**

- Diagnosis of COPD (must not be used for asthma or acute exacerbations) inhaler

**Duration of Approval:** 1 year

## BETA ADRENERGICS – SHORT ACTING

**Drug Class:** Beta Adrenergics – Short Acting

**Preferred Agents:** *No Prior Authorization required*

albuterol HFA (except Prasco)  
Albuterol sulfate nebulizer solution  
Ventolin HFA® (MDI)  
Xopenex HFA® (MDI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Airsupra®  
albuterol HFA (manufactured by Prasco)  
levalbuterol HFA (MDI)  
levalbuterol nebulizer solution  
ProAir Digihaler® (DPI)  
ProAir Respiclick® (DPI)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a two-week trial with one preferred medication

### QUANTITY LIMITS

|                                 |                        |
|---------------------------------|------------------------|
| Airsupra (albuterol/budesonide) | 6 inhalers per 90 days |
|---------------------------------|------------------------|

**Duration of Approval:** 1 year

## BETA BLOCKERS

**Drug Class:** Beta Blockers

**Preferred Agents:** *No Prior Authorization required*

atenolol  
atenolol / chlorthalidone  
bisoprolol fumarate  
bisoprolol fumarate HCT  
carvedilol  
Hemangeol oral solution®  
labetalol

metoprolol / metoprolol XL  
metoprolol succinate  
metoprolol tartrate  
nadolol  
nebivolol  
propranolol / propranolol LA  
sotalol / sotalol AF

**Non-Preferred Agents:** *Prior Authorization Criteria below*

acebutolol  
Betapace® / Betapace AF®  
betaxolol  
Bystolic®  
carvedilol ER  
Inderal LA® / Inderal XL®  
Innopran XL®  
Kaspargo®  
Lopressor®

metoprolol HCT  
pindolol  
propranolol HCT  
Sotylize®  
Tenormin® / Tenoretic®  
timolol maleate  
Toprol XL®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**HEMANGEOL (PROPRANOLOL)**

- Maximum age of 1 year

**Duration of Approval:** 1 year

## BEYFORTUS/ NIRSEVIMAB-ALIP

**Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).**

**Drug Class** Antiviral Monoclonal Antibodies:

**FDA-approved uses:** Prevention of RSV lower respiratory tract disease in:

- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

**Available dosage forms:** Syringes: 50mg/0.5ml, 100mg/ml

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** FDA-approved uses as listed above
- Duration of approval:**
  - Planned cardiac surgery with cardiopulmonary bypass: 2 doses, to include 1 dose before surgery and 1 dose after surgery
  - All other requests: 1 dose
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Mother did not receive vaccination against RSV in the 2<sup>nd</sup> or 3<sup>rd</sup> trimester; **AND**
  - Patient is < 8 months of age and born during (or entering) their first respiratory syncytial virus (RSV) season and has not received a previous dose of Beyfortus; **OR**
  - Patient is up to 24 months of age entering their second RSV season and is at increased risk of severe RSV disease such as but not limited to:
    - patient has chronic lung disease (CLD) and they required medical support during the 6-month period before the start of the second RSV season; **OR**
    - patient has congenital heart disease (CHD); **OR**
    - patient is immunocompromised; **OR**
    - patient has neuromuscular disorder; **OR**
    - patient has cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or weight for length < 10<sup>th</sup> percentile; **OR**
    - patient is Alaska Native; **OR**
    - patient is American Indian; **AND**
  - Patient has not received 5 doses of palivizumab (Synagis®) for the current RSV season

## **BILE SALTS**

**Drug Class:** Bile Salts

**Preferred Agents:** *No Prior Authorization required*

ursodiol capsules (generic for Actigall)  
ursodiol tablets

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Reltone®  
Urso Forte®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure on a one-month trial of one preferred medication

**Duration of Approval:** 1 year

## **BPH AGENTS – 5-ALPHA REDUCTASE (5AR) INHIBITORS**

**Drug Class:** BPH Agents – 5-Alpha Reductase (5AR) Inhibitors

**Preferred Agents:** *No Prior Authorization required*

dutasteride  
finasteride 5mg (generic for Proscar®)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Avodart®  
dutasteride/tamsulosin  
Proscar®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication
- **See additional medication-specific criteria below:**

**Duration of Approval:** 1 year (unless specified in drug specific criteria)

## **BPH AGENTS – ALPHA BLOCKERS**

**Drug Class:** BPH Agents – Alpha Blockers

**Preferred Agents:** *No Prior Authorization required*

Alfuzosin tablet  
Doxazosin tablet  
Prazosin capsule  
Tamsulosin capsule  
Terazosin capsule

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Cardura® tablet  
Cardura XR® tablet  
Flomax® capsule  
Minipress® capsule  
Rapaflo® capsule  
Silodosin (generic for Rapaflo) capsule  
Tezruly (terazosin) oral solution

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Therapeutic failure with a one-month trial with one preferred medication
- **See additional medication-specific criteria below:**

***Tezruly (terazosin) oral solution:***

- Patient is  $\geq 18$  years of age; AND
- Quantity Limit: 20mg/day; AND
- Patient is unable to swallow a solid oral dosage form of generic terazosin

**Duration of Approval:** 1 year, unless otherwise noted in drug-specific criteria

## BRONCHITOL® / MANNITOL

**Drug Class:** Mucolytic agent

**FDA-approved uses:** Bronchitol is a sugar alcohol indicated as add-on maintenance therapy to improve pulmonary function in adult patients 18 years of age and older with cystic fibrosis.

**Available dosage forms:** Bronchitol (mannitol) inhalation powder, 40mg of mannitol per capsule supplied in cartons containing 10, 140 or 560 capsules in blister packs co-packaged with 1, 1, and 4 inhalers respectively in a carton.

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Cystic fibrosis
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** for up to 1 year
- Prescriber Specialty:** Pulmonologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Prescriber attestation that the Bronchitol Tolerance Test (BTT) has been performed to confirm the patient is suitable for Bronchitol therapy;
  - Trial and failure of hypertonic saline;
  - Bronchitol will be used as add-on maintenance therapy to improve pulmonary function
- Quantity:** Maximum 560 capsules per 28 days
- Age:** 18 years and older
- Route of Administration:** Oral

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider attestation that member has had positive response to treatment;
  - Patient did not experience event of hemoptysis (coughing up blood)

### **Contraindications/Exclusions/Discontinuation:**

- Non-FDA-approved indications
- Hypersensitivity to mannitol or to any of the capsule components
- Failure to pass the BRONCHITOL Tolerance Test (BTT)

### **Other special considerations:**

- Patient is also using bronchodilator (A short-acting bronchodilator should be administered 5-15 minutes before every dose of Bronchitol)

## CALCIUM CHANNEL BLOCKERS - DIHYDROPYRIDINE

**Drug Class:** Calcium Channel Blockers - Dihydropyridine

**Preferred Agents:** *Clinical Prior Authorization below*

amlodipine besylate  
nifedipine / nifedipine SA  
Norliqva®

**Preferred Agent Medication Specific Criteria:**

**NORLIQVA® SUSPENSION (AMLODIPINE)**

- Patient age of 6 years or greater; **AND**
- Allow if patient has swallowing difficulties

**Non-Preferred Agents:** *Prior Authorization Criteria below*

felodipine ER  
isradipine  
Katerzia®  
levamlodipine  
nicardipine  
nisoldipine  
Norvasc®  
Procardia XL®  
Sdamlo®  
Sular®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**KATERZIA® SUSPENSION (AMLODIPINE)**

- Patient age of 6 years or greater; **AND**
- Allow if patient has swallowing difficulties; **AND**
- Trial and failure of the preferred amlodipine oral solution

**SDAMLO® SUSPENSION (AMLODIPINE BESYLATE)**

- Patient age of 6 years or greater; **AND**
- Allow if patient has swallowing difficulties; **AND**
- Trial and failure of the preferred amlodipine oral solution

**Duration of Approval:** 1 year

## CALCIUM CHANNEL BLOCKERS – NON-DIHYDROPYRIDINE

**Drug Class:** Calcium Channel Blockers – Non-Dihydropyridine

**Preferred Agents:** *No Prior Authorization required*

Diltiazem tablet / diltiazem XR / diltiazem ER capsule  
Taztia XT® capsule  
verapamil / verapamil ER tablet

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Cardizem® tablet / Cardizem LA® tablet / Cardizem CD® capsule  
diltiazem LA tablet  
Matzim LA® tablet  
Tiadylt ER® capsule  
Tiazac® capsule  
verapamil ER capsules  
Verelan PM® pellet capsules  
verapamil cap 24-hr pellet capsules

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## CAMZYOS / MAVACAMTEN

**Drug Class:** Cardiac Myosin Inhibitors

**FDA-approved uses:** CAMZYOS is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.

**Available dosage forms:** Tablets 2.5mg, 5mg, 10mg and 15mg

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (HCM)
- Duration of Approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:**
  - Prescribed by a cardiologist; **OR**
  - Prescribed in consultation with a cardiologist: Identify Cardiologist Name & NPI: \_\_\_\_\_
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Member has a left ventricular ejection fraction (LVEF) of  $\geq 55\%$ ; **AND**
  - Prescriber attests that the member will not be prescribed disopyramide, ranolazine, or combination therapy of beta blocker and calcium channel blocker, while the member is receiving Camzyos; **AND**
  - For females of childbearing potential, a pregnancy test is performed and is negative before starting therapy. **AND**
  - Attestation provided of patient, provider, and pharmacy enrollment in Camzyos Risk Evaluation and Mitigation Strategy (REMS) Program
- Quantity:** 30 capsules per 30 days
- Age:**  $\geq 18$  years of age

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g., Labs, Medical Record, Special Studies):
  - Prescribed by a cardiologist; **OR**
  - Prescribed in consultation with a cardiologist: Identify Cardiologist Name & NPI: \_\_\_\_\_
- Prescriber attests to positive clinical response or stable disease; **AND**
- Prescriber attests that the member will not be prescribed disopyramide, ranolazine, or combination therapy of beta blocker and calcium channel blocker, while the member is receiving Camzyos; **AND**
- Prescriber attests that the member is not pregnant; **AND**
- LVEF is  $\geq 50\%$

**Contraindications/Exclusions/Discontinuation:**

- Concomitant use of moderate to strong CYP2C19 inhibitors or strong CYP3A4 inhibitors;
- Concomitant use of moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers
- Pregnancy

**Other special considerations:**

- REMS program: Prescribers must be certified by enrolling in the REMS program. Patients must also enroll in the REMS program and comply with monitoring requirements. Pharmacies must be certified to dispense medication by enrolling in the REMS program.
- Verify pregnancy status prior to treatment initiation; pregnancy should be excluded prior to treatment initiation.

## CEPHALOSPORINS

### **Drug Class:**

- Cephalosporins - 1st Generation
- Cephalosporins - 2nd Generation
- Cephalosporins - 3rd Generation

### ❖ **CEPHALOSPORINS - 1ST GENERATION**

**Preferred Agents:** *No Prior Authorization required*

cefadroxil capsules  
cefadroxil suspension  
cephalexin

**Non-Preferred Agents:** *Prior Authorization Criteria below*

cefadroxil tablets

### ❖ **CEPHALOSPORINS - 2ND GENERATION**

**Preferred Agents:** *No Prior Authorization required*

cefuroxime  
cefprozil tablet  
cefprozil suspension

**Non-Preferred Agents:** *Prior Authorization Criteria below*

cefaclor  
cefaclor ER

### ❖ **CEPHALOSPORINS - 3RD GENERATION**

**Preferred Agents:** *No Prior Authorization required*

cefdinir capsules, suspension  
cefixime capsules

❖ **CEPHALOSPORINS - 3RD GENERATION, continued**  
**Non-Preferred Agents:** *Prior Authorization Criteria below*

cefixime suspension  
 cefpodoxime tablets  
 cefpodoxime suspension

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection caused by an organism resistant to the preferred cephalosporins; **OR**
- Therapeutic failure (duration = 3 days) with any two preferred cephalosporins medications

**QUANTITY LIMITS**

|  |             |
|--|-------------|
| cefaclor caps ( <i>Ceclor</i> ®)         | 42 per fill |
| cefaclor ER tabs ( <i>Ceclor CD</i> ®)   | 42 per fill |
| cefadroxil caps/tabs ( <i>Duricef</i> ®) | 28 per fill |
| cefdinir tabs ( <i>Omnicef</i> ®)        | 28 per fill |
| cefpodoxime tabs ( <i>Vantin</i> ®)      | 28 per fill |
| cefprozil tabs ( <i>Cefzil</i> ®)        | 28 per fill |
| ceftibuten caps ( <i>Cedax</i> ®)        | 14 per fill |
| cefuroxime tabs ( <i>Ceftin</i> ®)       | 42 per fill |

**Duration of Approval:** Date of service

## COLONY STIMULATING FACTORS

**Drug Class:** Colony Stimulating Factors

**Preferred Agents:** *No Prior Authorization required*

Fulphila®  
 Flynetra®  
 Neupogen®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                         |            |
|-------------------------|------------|
| Granix®                 | Nyvepria®  |
| Leukine®                | Releuko®   |
| Neulasta® syringe, vial | Stimufend® |
| Neulasta® Onpro Kit     | Udenyca®   |
| Nivestym®               | Zarxio®    |
| Nypozi®                 | Ziextenzo® |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications, **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication
- **See additional medication-specific criteria below:**

**Quantity Limitations:**

|                                 |                     |
|---------------------------------|---------------------|
| Fulphila 6mg/0.6ml Syringe      | 0.6 mls per 14 days |
| Flynetra 6mg/0.6ml Syringe      | 0.6 mls per 14 days |
| Neulasta 4mg/0.4ml Vial         | 0.4 mls per 14 days |
| Neulasta 6mg/0.6ml Syringe      | 0.6 mls per 14 days |
| Neulasta Onpro 6mg/0.6ml Kit    | 0.6 mls per 14 days |
| Nyvepria 6mg/0.6ml Syringe      | 0.6 mls per 14 days |
| Stimufend 6mg/0.6ml Syringe     | 0.6 mls per 14 days |
| Udenyca 6mg/0.6ml Auto Injector | 0.6 mls per 14 days |
| Udenyca 6mg/0.6ml Syringe       | 0.6 mls per 14 days |
| Udenyca 6mg/0.6ml OnBody        | 0.6 mls per 14 days |
| Ziextenzo 6mg/0.6ml Syringe     | 0.6 mls per 14 days |
| Zarxio 480mcg/0.8ml Syringe     | 45 mls per 30 days  |
| Zarxio 300mcg/0.5ml Syringe     | 45 mls per 30 days  |

**Duration of Approval:** 1 year

## COMBINATION BENZOYL PEROXIDE AND CLINDAMYCIN

**Drug Class:** Combination Benzoyl Peroxide and Clindamycin

**Preferred Agents:** *No Prior Authorization required*

clindamycin / benzoyl peroxide

**Non-Preferred Agents:** *Prior Authorization Criteria below*

clindamycin / benzoyl peroxide (generic Onexton)  
Neuac 1.25% kit®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication

**Duration of Approval:** 1 year

## COMBINATION NASAL SPRAYS

**Drug Class:** Combination Nasal Sprays

**Preferred Agents:**

**Non-Preferred Agents:** *Prior Authorization Criteria below*

azelastine/fluticasone spray  
Dymista®  
Ryaltris®

**Non-Preferred Agent PA Criteria:**

- 1 month trial and failure of one preferred nasal antihistamine; **AND**
- 1 month trial and failure of one preferred nasal corticosteroid

**Duration of Approval:** 1 year

## CORLANOR® / IVABRADINE

**Drug Class:** Hyperpolarization-activated cycle nucleotide-gated channel blocker

**FDA-approved uses:** Heart failure, chronic, and heart failure, chronic, due to dilated cardiomyopathy

**Available dosage forms:**

- Oral solution 1mg/1ml
- Oral tablet: 5mg. 7.5mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Heart failure
- Duration of approval:** 12 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of stable symptomatic chronic heart failure (NYHA class II, III or IV) **AND**
  - Left ejection fraction  $\leq 35\%$  **AND**
  - The patient is in sinus rhythm **AND**
  - Patient has a resting heart rate  $>70$  beats per minute **AND**
  - One of the following:
    - Patient is on maximum tolerated doses of beta-blockers (e.g. carvedilol, metoprolol, succinate, bisoprolol) **OR**
    - Patient has a contraindication to or intolerance to beta-blocker therapy

**OR**

- Pediatric patients ages 6 months and older:
  - Diagnosis of stable symptomatic heart failure due to dilated cardiomyopathy (DCM) **AND**
  - Patient is in sinus rhythm **AND**
  - Patient has an elevated heart rate for age

**Criteria for continuation of therapy:**

- Attestation to positive clinical response to therapy

## DARAPRIM® / PYRIMETHAMINE

**Drug Class:** Antimalarials

**FDA-approved uses:**

- Treatment of toxoplasmosis: Daraprim is indicated for the treatment of toxoplasmosis when used conjointly with a sulfonamide.
- Treatment of acute Malaria: Daraprim is indicated for the treatment of acute malaria. It should not be used alone to treat acute malaria. Fast-acting schizonticides such as chloroquine or quinine are indicated and preferable for the treatment of acute malaria. However, conjoint use of Daraprim with a sulfonamide will initiate transmission control and suppression of susceptible strains of plasmodia.
- Malaria prophylaxis: Daraprim is indicated for the chemoprophylaxis of malaria due to susceptible strains of plasmodia. However, resistance to pyrimethamine is prevalent worldwide. It is not suitable as a prophylactic agent for travelers to most areas.

**Available dosage forms:** 25mg Tablet

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Treatment of Toxoplasmosis
  - Secondary prevention of Toxoplasmosis in patients with HIV
  - Prevention of pneumocystis pneumonia in patients with HIV
- Duration of Approval:**
  - **Initial Authorization:**
    - Toxoplasmosis – 6 weeks
    - Pneumocystis prophylaxis – 3 months
  - **Continuation of Therapy:**
    - Toxoplasmosis – 6 months
    - Pneumocystis – 3 months
- Prescriber Specialty:** infectious disease
- Documentation Requirements:** (e.g. Labs, Medical Record, Special Studies):
  - For Pneumocystis diagnosis ONLY: TMP/SMX, atovaquone, and dapsone
  - For Pneumocystis prophylaxis (ONE of the following):
    - CD4 count <200 cells/microL
    - Oropharyngeal candidiasis
    - CD4 count percentage <14 percent
    - CD4 cell count between 200 and 250 cells/microL IF frequent monitoring (eg, every three months) of CD4 cell counts is not possible

- Quantity:**
  - Toxoplasmosis (induction-dose): 90 tablets per 30 days
  - Toxoplasmosis (maintenance-dose): 60 tablets per 30 days
  - Pneumocystis prophylaxis: 12 tablets per 28 days
- Gender:** male and female
- Route of Administration:** oral
- Place of Service:** outpatient

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - For Toxoplasmosis prophylaxis, after initial 6 weeks of induction treatment (ONE of the following):
    - Patient remains symptomatic
    - Patient is NOT receiving antiretroviral therapy (ART)
    - Patient has a detectable HIV viral load
    - Patient has maintained a CD4 count >200 cells/microL for less than six months
  - For Pneumocystis prophylaxis (ONE of the following):
    - CD4 count <200 cells/microL
    - Oropharyngeal candidiasis
    - CD4 count percentage <14 percent
    - CD4 cell count between 200 and 250 cells/microL IF frequent monitoring (eg, every three months) of CD4 cell counts is not possible

**Contraindications/Exclusions/Discontinuation:**

- Megaloblastic anemia due to folate deficiency
- Secondary prophylaxis of Toxoplasmosis in patients with a CD4 count >200 cells/microL for longer than 6 months and a sustained HIV viral load
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

**Other special considerations:**

- Daraprim is no longer recommended for malaria treatment or prophylaxis and treatment of malaria is very individualized.
- Refer to the CDC website for recommendations for treatment and prevention of malaria.

**References**

1. Gandhi RT. Toxoplasmosis in HIV-infected patients. Waltham, MA: UptoDate; Last modified September 21, 2015. [http://www.uptodate.com/contents/toxoplasmosis-in-hiv-infected-patients?source=search\\_result&search=daraprim&selectedTitle=6%7E47](http://www.uptodate.com/contents/toxoplasmosis-in-hiv-infected-patients?source=search_result&search=daraprim&selectedTitle=6%7E47). Accessed September 25, 2015.

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## DESMOPRESSIN NASAL SPRAY

**Drug Class** (ETC\_Name): Antidiuretic and vasopressor hormones

**FDA-approved uses:**

Arginine Vasopressin Disorder – Desmopressin Nasal Spray

**Available dosage forms:**

Desmopressin Nasal Spray – 0.1 mg/ml solution, 10 mcg/0.1 ml spray

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Arginine Vasopressin Disorder (formally known as Central Diabetes Insipidus)
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** for up to 1 year
- Prescriber Specialty:** Must be prescribed by, or in consultation with, an endocrinologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation of Arginine Vasopressin Disorder/Central Diabetes Insipidus; **AND**
  - Clinical documentation of inadequate response to a 3-month trial of a maximum tolerated dose of Desmopressin tablets; **OR**
  - Clinical documentation of contraindication to Desmopressin tablets; **OR**
  - Prescriber attests that the patient is unable to swallow tablets; **AND**
  - Prescriber attests the patient has been counseled on symptoms associated with hyponatremia; **AND**
  - Prescriber attests the patient has a confirmed absence of all contraindications to desmopressin nasal spray, including: hypersensitivity to desmopressin acetate or product components, existing or history of hyponatremia, or Renal impairment defined as CrCl <50 mL/min.
- Quantity:**
- Age:** 4 years or older
- Gender:**
- Route of Administration:** intranasal
- Place of Service:**

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation of symptom improvement since initiating the requested drug, such as reduction in polyuria, nocturia, and/or polydipsia; **AND**
  - Prescriber attests the patient has a confirmed absence of all contraindications to desmopressin nasal spray, including: hypersensitivity to desmopressin acetate or product components, existing or history of hyponatremia, or Renal impairment defined as CrCl <50 mL/min.

## DIRECT RENIN INHIBITORS

**Drug Class:** Direct Renin Inhibitors

**Preferred Agents:** *No Prior Authorization required*

**Non-Preferred Agents:** *Prior Authorization Criteria below*

aliskiren  
Tekturna®

**Non-Preferred Agent PA Criteria:**

- Trial/failure on an ACE inhibitor or an ARB or clinical rationale why neither is appropriate.

**Duration of Approval:** 1 year

## ELMIRON® / PENTOSAN POLYSULFATE SODIUM

**Drug Class:** Urinary tract analgesic agents

**FDA-approved uses:** indicated for the relief of bladder pain or discomfort associated with interstitial cystitis.

**Available dosage forms:** 100mg Capsules

### **Coverage Criteria/Limitations for initial authorization**

- Diagnoses:** interstitial cystitis
- Duration of Therapy**
  - Initial Approval: 3 months
  - Continuation of Therapy: 3 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of interstitial cystitis confirmed

### **Criteria for continuation of Therapy**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - If pain has not improved after 3 months of therapy and if limiting adverse events have not occurred, pentosan may be continued for an additional 3 months. The clinical benefit of treatment beyond 6 months for patients whose pain has not improved is not known.

### **Contraindications/Exclusions/Discontinuation:**

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## ENDARI / L-GLUTAMINE

**Drug Class:** Sickle Cell Anemia Agents (N1H)

**FDA-approved uses:**

Endari is an amino acid indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older.

**Available dosage forms:**

Oral Powder: 5 grams of L-glutamine powder per paper-foil-plastic laminate packet.

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Sickle Cell Disease
- Duration of approval:**
  - **Initial authorization:** 1-year duration upon approval
    - Documented diagnosis of sickle cell disease **AND**
    - Request is for an FDA approved dose **AND**
    - Patient has had an inadequate response to a maximally tolerated dose of hydroxyurea **OR**
    - Justification provided regarding intolerance, contraindication, or patient/family refusal to the use of hydroxyurea
  - **Continuation of Therapy:** 1-year approval
    - Prescriber attestation that member is tolerating current therapy **AND**
    - Member continues on an FDA approved dose.
- Prescriber Specialty:** Must be prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Medical Record indicating
    - Sickle Cell Disease
- Quantity:** Maximum of 180 packets/30 days
- Age:** 5 years of age and older
- Route of Administration:** Oral
- Place of Service:** Outpatient pharmacy

**Contraindications/Exclusions/Discontinuation:**

- No contraindications to report at this time.
- Warnings/Precautions: Use with caution in patients with hepatic and/or renal impairment. No specific dosage adjustments are documented.
- Safety has not been established in patients younger than 5 years old.

## ENSPRYNG/ SATRALIZUMAB-MWGE

**Drug Class:** Interleukin-6 (IL-6) Receptor Inhibitor

**FDA-approved uses:** Neuromyelitis optica spectrum disorder, Anti-aquaporin-4 (AQP4) antibody positive

**Available dosage forms:** Subcutaneous injection: 120mg/ml single-dose prefilled syringe

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Neuromyelitis optica spectrum disorder
- Duration of approval:**
  - **Initial authorization:** 12 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:** Prescribed by, or in consultation with, a neurologist or other provider who specializes in the treatment of NMOSD
- Documentation Requirements:**
  - Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD; **AND**
  - Clinical evidence of at least 1 documented relapse (including first attack) in last 12 months; **AND**
  - Prescriber attests that the member has been assessed for the following baseline values prior to first dose:
    - Hepatitis B virus
    - Tuberculosis
    - Liver transaminase levels
    - Neutrophil Count; **AND**
  - Prescriber attests that the member has or will avoid vaccinations within recommended time frames prior to initiation of Enspryng (see below); **AND**
  - Documented trial and failure or medical contraindication to one of the following:
    - Rituximab
    - Azathioprine
    - Mycophenolate mofetil
- Quantity:** 120 mg/mL by subcutaneous (SQ) injection at Weeks 0, 2, and 4, followed by a maintenance dosage of 120 mg every 4 weeks.
- Age:** 18 years and older
- Route of Administration:** Subcutaneous Injection
- Place of Service:** Self-administered at home

### **Criteria for continuation of therapy:**

- Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)
- Request is for an FDA approved/medically accepted dose

**Contraindications/Exclusions/Discontinuation:**

- Prescriber attests that member has not received (or will not receive) live or attenuated-live virus vaccines within 4 weeks prior to initiation of Enspryng and non-live vaccines at least 2 weeks prior to initiation of Enspryng.

**Other special considerations:**

- Pregnancy Category: Fetal risk cannot be ruled out.
- Breast Feeding: Infant risk cannot be ruled out.

## ENTOCORT EC® / BUDESONIDE EC

**Drug Class:** Crohn disease - Oral

**FDA-approved uses:** Crohn disease (mild to moderate)

**Available dosage forms:** 3mg EC Capsule

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** active Crohn disease
- Duration of approval:**
  - **Initial authorization:** 16 weeks of 9mg once daily
  - **Continuation of Therapy:** 3 months of 6mg once daily, followed by a 3mg one daily for one month
- Prescriber Specialty:** Gastrointestinal (or in collaboration with GI)
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Intolerance to or history of unacceptable side effects to prednisone (or other systemic steroids)
- Quantity:**
  - 16 weeks/4months – 9mg once daily (induction)
  - 3 months – 6mg once daily (maintenance)
  - 1 month – 3mg once daily (taper)

## EOHILIA / BUDESONIDE

**Drug Class** : Corticosteroid

**FDA-approved uses:** Eohilia is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE)

**Available oral dosage forms:** 2 mg/10 mL oral suspension; 10 mL single-dose stick packs in a 60 count carton. Recommended dosage: 2 mg swallowed twice daily for 12 weeks

**Coverage Criteria/Limitations for authorization:**

- Diagnoses:** Eosinophilic esophagitis
- Duration of approval:**
  - 3 months
- Prescriber Specialty:** Gastroenterologist or Allergist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies, Provider attestation):
  - Patient age  $\geq$  11 years; **AND**
  - Therapy is prescribed by or in consultation with a gastroenterologist or allergist; **AND**
  - The patient has at least 15 eosinophils/high-power field (hpf) in the esophagus as confirmed by a biopsy; **AND**
  - Patient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor
- Age:** 11 years of age and older
- Quantity Limit:** 20mL/day for three months

**Contraindications/Exclusions/Discontinuation:**

Limitations of use: Eohilia has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks

## EPINEPHRINE SELF-ADMINISTERED

**Drug Class:** Epinephrine Self-Administered

**Preferred Agents:** *No Prior Authorization required*

epinephrine (generic for Adrenaclick® by Amneal)  
epinephrine (generic for Epi Pen®/EpiPen Jr® by Teva)  
epinephrine (generic for Epi Pen®/EpiPen Jr® by Mylan)  
Epi Pen®, Epi Pen Jr®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Auvi-Q®  
Neffy®

**Non-Preferred Agent PA Criteria:**

- Therapeutic failure or contraindication to use of a preferred medication
- **See additional medication-specific criteria below:**

**NEFFY® (EPINEPHRINE)**

- Patient weighs at least 30kg

### QUANTITY LIMITS

|   |            |
|---|------------|
| epinephrine (generic for Adrenaclick®)            | 4 per fill |
| Auvi-Q®   | 4 per fill |
| Epinephrine (generics for EpiPen® and EpiPen Jr®) | 4 per fill |
| EpiPen® (epinephrine)                             | 4 per fill |
| EpiPen Jr® (epinephrine)                          | 4 per fill |
| Neffy Nasal Spray (epinephrine)                   | 4 per fill |

**Duration of Approval:** 1 year

## EXSERVAN FILM, TIGLUTIK SUSPENSION / RILUZOLE

**Drug Class:** ALS Agent - Benzothiazoles

**FDA-approved uses:** treatment of amyotrophic lateral sclerosis (ALS)

**Available dosage forms:** Exservan 50 mg Film, Tiglutik 50mg/10ml Suspension

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** ALS
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by or in consultation with a neurologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient cannot swallow tablets;
- Age:** ≥ 18 years old

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient is receiving clinical benefit from therapy

## GASTROINTESTINAL ANTIBIOTICS

**Drug Class:** Gastrointestinal Antibiotics

**Preferred Agents:** *No Prior Authorization required*

Dificid Tablets®  
metronidazole 250mg and 500mg tablets  
neomycin tablets  
tinidazole  
vancomycin capsules  
vancomycin solution

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Aemcolo®  
Dificid Suspension®  
Firvanq®  
fidaxomicin  
Flagyl® tablets and capsules  
Likmez®  
metronidazole capsules  
metronidazole 125mg tablets  
nitazoxanide tablets  
Vancocin®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with one preferred medication
- **See additional medication-specific criteria below:**

**AEMCOLO® (RIFAMYCIN)**

- Travelers' diarrhea caused by noninvasive strains of *E. coli* and age ≥18 years of age (PDL criteria do not apply); **AND**
- The patient has had an inadequate response, intolerance or contraindication to azithromycin or a fluoroquinolone
- Quantity Limit: 12 tablets per claim
- **Length of authorization: 3 days**

**DIDICID® (FIDAXOMICIN) 40 MG/ML ORAL SUSPENSION**

- Maximum patient age = 17 years

**LIKMEZ® (METRONIDAZOLE)**

- PDL criteria may be bypassed if patient is less than 12 years of age or unable to swallow tablets
- Quantity Limit: 400 mL per 10 days
- Length of approval: Duration of the prescription

**NITAZOXANIDE (ALINIA®) (PDL criteria do not apply)**

- Tablets:
  - For treatment of diarrhea caused by *Cryptosporidium parvum* or *Giardia lamblia* **AND**
  - The patient has had a trial on metronidazole or a clinical reason why it cannot be tried
  - length of authorization = 1 month
  - Quantity limit = 6 tablets per rolling 30 days)

**Duration of Approval:** 1 year, unless otherwise noted in drug-specific criteria

## GI MOTILITY, CHRONIC

### **Drug Class:**

- GI Motility, Chronic - Chronic idiopathic constipation (CIC)
- GI Motility, Chronic - Irritable bowel syndrome with constipation (IBS-C)
- GI Motility, Chronic - Irritable bowel syndrome with diarrhea (IBS-D)
- GI Motility, Chronic - Opioid-induced constipation (OIC)

### ❖ **GI MOTILITY, CHRONIC - CHRONIC IDIOPATHIC CONSTIPATION (CIC)**

#### **Preferred Agents:**

Linzess®  
lubiprostone

#### **Non-Preferred Agents:** *Prior Authorization Criteria below*

Amitiza®  
Motegrity®  
prucalopride

### ❖ **GI MOTILITY, CHRONIC - IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C)**

#### **Preferred Agents:**

Linzess®  
lubiprostone

#### **Non-Preferred Agents:** *Prior Authorization Criteria below*

Amitiza®  
Ibsrela®

### ❖ **GI MOTILITY, CHRONIC - IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D)**

#### **Preferred Agents:** *Clinical Prior Authorization below*

diphenoxylate/atropine (generic Lomotil®)  
loperamide (generic Imodium®)

#### **Non-Preferred Agents:** *Prior Authorization Criteria below*

alosetron  
Lotronex®  
Viberzi®

## ❖ GI MOTILITY, CHRONIC - OPIOID-INDUCED CONSTIPATION (OIC)

### Preferred Agents:

lubiprostone

### Non-Preferred Agents: *Prior Authorization Criteria below*

Amitiza®  
Symproic®  
Movantik®

### PA Criteria:

#### Non-Preferred Agents

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication within the same subclass
- **See additional medication-specific criteria below:**

### Medication-Specific Criteria

#### **AMITIZA® (LUBIPROSTONE)**

- Patient is ≥ 18 years of age; **AND**
- Quantity limit of 2 capsules per day

#### **IBSRELA® (TENAPANOR)**

- Diagnosis of irritable bowel syndrome with constipations (IBS-C): **AND**
- Patient is ≥ 18 years of age **AND**
- Therapeutic failure after one-month trial of one preferred agent of IBS-C
- Quantity Limit = 2 tablets/day

#### **LINZESS® (LINACLOTIDE)**

- Patient is ≥ 6 years of age; **AND**
- Quantity limit of 1 capsule per day

#### **LOTRONEX® (ALOSETRON)**

- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Therapeutic failure after one-month trial of diphenoxylate/atropine or loperamide
- Member is female

**MOTEGRITY® (PRUCALOPRIDE)**

- Diagnosis of chronic idiopathic constipation (CIC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Therapeutic failure after one-month trial of one preferred agent for CIC

**SYMPROIC® (NALDEMEDINE TOSYLATE)**

- Diagnosis of opioid induced constipation (OIC); **AND**
- Therapeutic failure after one-month trial of one preferred agent for OIC

**VIBERZI® (ELUXADOLINE)**

- Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) **AND**
- Therapeutic failure after one-month trial of diphenoxylate/atropine or loperamide
- Quantity limit = 2 tablets/day

**Duration of Approval:** Up to 1 year

## GLAUCOMA

### **Drug Class:**

- Glaucoma – Alpha-2 Adrenergics
- Glaucoma – Beta Blockers
- Glaucoma – Carbonic Anhydrase Inhibitors
- Glaucoma – Combination Alpha-2 Adrenergic-Beta Blocker
- Glaucoma – Prostaglandin Analogues
- Glaucoma – Rho Kinase Inhibitors

### ❖ **GLAUCOMA – ALPHA-2 ADRENERGICS**

**Preferred Agents:** *No Prior Authorization required*

Apraclonidine  
brimonidine tartrate 0.2%

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Alphagan P®  
brimonidine tartrate 0.1%  
brimonidine tartrate 0.15%  
lopidine®

### ❖ **GLAUCOMA – BETA BLOCKERS**

**Preferred Agents:** *No Prior Authorization required*

Betoptic S®  
Carteolol  
timolol maleate (generic for Timoptic®)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Betaxolol  
Betimol®  
Istalol®  
Levobunolol  
timolol (generic for Betimol®)  
timolol maleate (generic for Istalol®)  
timolol ocudose (generic for Timoptic Ocudose®)  
Timoptic®/ Timoptic Ocudose®  
Timoptic XE®

❖ **GLAUCOMA – CARBONIC ANHYDRASE INHIBITORS**

**Preferred Agents:** *No Prior Authorization required*

brinzolamide  
dorzolamide  
dorzolamide / timolol (generic Cosopt®)  
Simbrinza®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Azopt®  
Cosopt®/ Cosopt PF®  
dorzolamide / timolol PF (generic for Cosopt PF®)

❖ **GLAUCOMA – COMBINATION ALPHA-2 ADRENERGIC-BETA BLOCKER**

**Preferred Agents:** *No Prior Authorization required*

Combigan®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

brimonidine-timolol

❖ **GLAUCOMA – PROSTAGLANDIN ANALOGUES**

**Preferred Agents:** *No Prior Authorization required*

latanoprost

**Non-Preferred Agents:** *Prior Authorization Criteria below*

bimatoprost (generic for Lumigan®)  
lyuzeh®  
Lumigan®  
tafluprost (generic for Zioptan®)  
Travatan Z®  
travoprost (generic for Travatan®)  
Vyzulta®  
Xalatan®  
Xelpros®  
Zioptan®

❖ **GLAUCOMA – RHO KINASE INHIBITORS**

**Preferred Agents:** *No Prior Authorization required*

Rhopressa®

Rocklatan®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication within the same subclass

**Duration of Approval:** 1 year

## GLP1s FOR CARDIOVASCULAR RISK REDUCTION

**Drug Class:** GLP1s for Cardiovascular Risk Reduction

**Preferred Agents:**

**Non-Preferred Agents:** *Clinical Prior Authorization below*

*Wegovy® (semaglutide)*

**Clinical PA Criteria:**

### **Initial**

- Prescriber attests that the patient will not use Wegovy concurrently with another GLP-1 agonist; **AND**
- Prescriber attests that the patient will not use Wegovy concurrently with a non-GLP1 weight loss medication; **AND**
- Prescriber attests that the patient will not use Wegovy concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin); **AND**
- Patient  $\geq 18$  years of age; **AND**
- Prescriber attests patient has an initial body mass index [BMI]  $\geq$  than 27 kg/m<sup>2</sup>; **AND**
- Prescriber attests patient has established cardiovascular disease (e.g., Wegovy is being prescribed for cardiovascular risk reduction in patients with prior myocardial infarction, prior stroke or peripheral arterial disease); **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

### **Renewal**

- Prescriber attests that the patient is currently established on the medication and has established cardiovascular disease (e.g., Wegovy is being prescribed for cardiovascular risk reduction in patients with prior myocardial infarction, prior stroke or peripheral arterial disease); **AND**

- Prescriber provides clinical documentation demonstrating weight, associated with the renewal request and showing that the patient has maintained a weight loss of  $\geq 5\%$  from baseline weight at initiation of therapy.

**QUANTITY LIMITS**

|  |                           |
|--|---------------------------|
| Wegovy (semaglutide) 0.25 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 0.50 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1 mg/0.5 mL pens    | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1.7 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 2.4 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Wegovy HD 7.2 mg/0.75 mL pen             | 3 mL per 28 days          |

**Duration of Approval:** Initial = 6 months, Renewal = 6 months

## GLP1s FOR MASH

**Drug Class:** GLP1s for MASH

**Preferred Agents:**

**Non-Preferred Agents:** *Clinical Prior Authorization below*

*Wegovy® (semaglutide)*

**Clinical PA Criteria:**

**Initial**

- Prescriber attest that the patient will not use Wegovy concurrently with a non-GLP1 weight loss medication; **AND**
- Prescriber attests that the patient will not use Wegovy concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin); **AND**
- Patient ≥ 18 years of age; **AND**
- Prescriber attests patient has an initial body mass index [BMI] ≥ than 27 kg/m<sup>2</sup>; **AND**
- Prescriber attests patient has noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

**Renewal**

- Prescriber attests that the patient is currently established on the medication and has noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); **AND**

- Prescriber provides clinical documentation demonstrating weight, associated with the renewal request and showing that the patient has maintained a weight loss of  $\geq 5\%$  from baseline weight at initiation of therapy.

**QUANTITY LIMITS**

|  |                           |
|--|---------------------------|
| Wegovy (semaglutide) 0.25 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 0.50 mg/0.5 mL pens | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1 mg/0.5 mL pens    | 2 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 1.7 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Wegovy (semaglutide) 2.4 mg/0.75 mL pens | 3 mL (4 pens) per 28 days |
| Wegovy HD 7.2 mg/0.75 mL pen             | 3 mL per 28 days          |

**Duration of Approval:** Initial = 6 months, Renewal = 6 months

## GLP1s FOR OBSTRUCTIVE SLEEP APNEA

**Drug Class:** GLP1s for Obstructive Sleep Apnea

**Preferred Agents:** *Clinical Prior Authorization below*

**Non-Preferred Agents:** *Clinical Prior Authorization below*

Zepbound® (tirzepatide)

### **Clinical PA Criteria:**

#### **Initial**

- Prescriber attests that the patient will not use Zepbound concurrently with another GLP-1 agonist; **AND**
- Prescriber attests that the patient will not use Zepbound concurrently with a non-GLP1 weight loss medication; **AND**
- Prescriber attests that the patient will not use Zepbound concurrently with a medication that contains a DPP-4 inhibitor (alogliptin, linagliptin, saxagliptin or sitagliptin); **AND**
- Patient  $\geq 18$  years of age; **AND**
- Prescriber attests patient has an initial body mass index [BMI]  $\geq$  than 27 kg/m<sup>2</sup>; **AND**
- Patient has a documented diagnosis of moderate to severe obstructive sleep apnea (OSA); **AND**
- For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this treatment; **AND**
- Prescriber attests that metabolic or other reason(s) for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, etc.); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability; **AND**
- Prescriber attests that patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted.

***MDHHS recommends that prescribers consider the benefits of a diabetes prevention program for their patients.***

#### **Renewal**

- Prescriber attests that the patient is currently established on the medication for a diagnosis of moderate to severe obstructive sleep apnea (OSA); **AND**
- Prescriber provides clinical documentation demonstrating weight associated with this renewal request and showing that the patient has maintained a weight loss of  $\geq 5\%$  from baseline weight at initiation of therapy.

**QUANTITY LIMITS**

|   |                                 |
|---|---------------------------------|
| Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials   | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials  | 2 mL (4 pens/vials) per 28 days |
| Zepbound (tirzepatide) 12.5 mg/0.5 mL pens      | 2 mL (4 pens) per 28 days       |
| Zepbound (tirzepatide) 15 mg/0.5 mL pens        | 2 mL (4 pens) per 28 days       |
| ZEPBOUND 2.5MG/DOS(10MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 5MG/DOSE (20MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 7.5MG/DOS(30MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 10MG/DOSE(40MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 12.5MG/DOS(50MG/2.4ML)                 | 2.4 ML (1 Kwikpen) per 28 days  |
| ZEPBOUND 15MG/DOSE(60MG/2.4ML)                  | 2.4 ML (1 Kwikpen) per 28 days  |

**Duration of Approval:** Initial = 6 months, Renewal = 6 months

## GLUCAGON AGENTS

**Drug Class:** Glucagon Agents

**Preferred Agents:** *No Prior Authorization required*

Baqsimi®  
Zegalogue®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Glucagon Emergency Kit (Amphastar and Fresenius)  
Gvoke Pen®  
Gvoke® Syringe, Kit, Vial

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- History of trial and failure with one preferred medication

**Quantity Limitations:**

|                         |                        |
|-------------------------|------------------------|
| BAQSIMI                 | 2 devices per 30 days  |
| GVOKE HYPOPEN, SYRINGES | 2 syringes per 30 days |
| GVOKE VIALS             | 2 vials per 30 days    |

**Duration of Approval:** 1 year

## GROWTH HORMONES

**Drug Class:** Growth Hormones

**Preferred Agents:** *Clinical Prior Authorization below*

Genotropin®  
Norditropin®  
Norditropin Flexpro®

**Clinical PA Criteria:**

- Requests must be submitted by an endocrinologist or nephrologist.
- Panhypopituitarism/Hypopituitarism – Cachexia, pituitary; Necrosis of pituitary (postpartum); Pituitary insufficiency NOS; Sheehan’s syndrome; Simmond’s disease and Growth Hormone Deficiency.
- Pituitary dwarfism – Isolated deficiency of (human) growth hormone [HGH]; Lorain-Levi dwarfism).
- Endocrine disorders – Other specified endocrine disorders: Pineal gland dysfunction; Progeria; Werner’s syndrome.
- Indeterminate sex and pseudo hermaphroditism – Gynandrisms; Hermaphroditism; Ovotestis; Pseudo hermaphroditism (male, female); Pure gonadal dysgenesis
- Gonadal dysgenesis – Turner’s Syndrome (female only); XO syndrome; Ovarian dysgenesis
- Noonan Syndrome – Norditropin® is the only medication with this indication.
- Prader-Willi Syndrome. Genotropin®, Norditropin FlexPro® and Omnitrope® are the only medications with this indication
- For Dx of Idiopathic Short Stature, individual medical record and necessity review will be required.
- **CKD – stage 1, 2 or 3 (CRI): Nutropin®** is the only medication with this indication
- **CKD – stage 4 or 5 (CRF or ESRD)**
- **SHOX: Humatrope®** is the only medication with this indication

**REQUIRED TESTING INFORMATION:**

- **Growth hormone stimulation testing:**
  1. Pituitary dwarfism: the patient must have failed **two** kinds of growth hormone stimulation tests for the diagnosis. Testing is required for pediatric, adolescent, and adult patients. For adolescent patients whose epiphyseal growth plates are closed and for adult patients, testing must be done after growth hormone therapy has been suspended for at least 3 months.
  2. Requester should document the kinds of stimulation tests performed, the result (lab value), reference range and date.
- **Bone age x-rays (required regardless of diagnosis; x-ray does not have to be performed within a specific time frame):**

**Clinical PA Criteria, continued**

- Pediatric patients - bone x-ray report is required **unless** the prescriber is a (pediatric) endocrinologist
- Adolescent patients (13 to 19 years of age)– bone x-ray report is required UNLESS the prescriber is a (pediatric) endocrinologist; the requester must also note whether or not the epiphyseal growth plates have closed.
- Adult patients – bone x-ray report is **NOT** required.
- **Papilledema:**
- Provider is aware of the risk of intracranial hypertension and the role of fundoscopic examination to assess and monitor for papilledema.
- For Idiopathic Short Stature, individual medical record and necessity review will be required.
- Requests that do not meet clinical criteria will require further review and must include the patient’s diagnosis including ICD-10, if available. Growth charts should be provided, if available, at time of review (ensure that the correct chart is being submitted based on the patient’s age – i.e., 0–3 vs 2–20) in addition to documentation of small for gestational age at birth, if appropriate.

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Humatrope®  
Ngenla®  
Nutropin AQ®  
Omnitrope®  
Serostim®  
Sogroya®  
Skytrofa®  
Zomacton®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication; **OR**
- The patient’s condition is clinically stable such that switching medications would cause deterioration in the condition
- See additional medication-specific criteria below:

**NGENLA® (SOMATROGON-GHLA)**

- Maximum patient age = 16 years

**SOGROYA® (SOMAPACITANB-BECO)**

- **Quantity Limit:** 8 mgs per week

**Duration of Approval:** 1 year

## H. PYLORI TREATMENT

**Drug Class:** H. pylori Treatment

**Preferred Agents:** *No Prior Authorization required*

Pylera®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

bismuth/metronidazole/tetracycline  
lansoprazole/amoxicillin/clarithromycin  
Omeclamox-PAK®  
Talicia  
Voquezna Dual Pak®  
Voquezna Triple Pak®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-course (e.g., 10-14 days) trial of the preferred agent

**Duration of Approval:** 1 year

## HEMATOPOIETIC AGENTS

**Drug Class:** Hematopoietic Agents

**Preferred Agents:** *Clinical Prior Authorization below*

Aranesp®  
Epogen®  
Retacrit®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Jesduvroq®  
Procrit®  
Vafseo

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication
- **See additional medication/diagnoses-specific criteria below:**

**CHRONIC KIDNEY DISEASE STAGE 3, STAGE 4 [CRF - CHRONIC RENAL FAILURE] AND STAGE 5 [ESRD END STAGE RENAL DISEASE] (EPOGEN®, PROCIT®, RETACRIT® AND ARANESP®):**

- Hemoglobin level < 10 g/dL before treatment with **Epogen®, Procrit®, Retacrit®, Aranesp®** or transfusions
- **RENEWAL:** CURRENT hemoglobin level < 12 g/Dl

**KIDNEY TRANSPLANT PATIENTS - TRANSPLANTED KIDNEY IS NOTED AS NOT YET FUNCTIONING TO ANTICIPATED POTENTIAL (EPOGEN®, PROCIT®, RETACRIT® AND ARANESP®):**

- < 1-year post transplant
- CURRENT hemoglobin level < 12 g/dL
- Length of Authorization: 6 months

**CHEMOTHERAPY OR RADIATION THERAPY CONFIRMED AS CURRENT (EPOGEN®, PROCIT®, RETACRIT® AND ARANESP® ONLY):**

- Hemoglobin level < 10 g/dL before beginning treatment with **Epogen®, Procrit®, Retacrit®, Aranesp®** or transfusions
- **RENEWAL:** CURRENT hemoglobin level < 12 g/dL

**ANEMIA IN AIDS PATIENTS: (EPOGEN<sup>®</sup>, PROCIT<sup>®</sup>, RETACRIT<sup>®</sup> ONLY)**

- Hemoglobin level < 10 g/dL

**ANEMIC PATIENTS SCHEDULED TO UNDERGO NON-CARDIAC, NON-VASCULAR SURGERY TO DECREASE NEED FOR TRANSFUSIONS: (EPOGEN<sup>®</sup>, PROCIT<sup>®</sup>, RETACRIT<sup>®</sup> ONLY).**

- Clinical rationale why alternative approaches such as donating own blood prior or transfusion is not an option.
- CURRENT hemoglobin level < 10 g/dL

**MYELOYDYSPLASIA AND MYELOYDYSPLASTIC SYNDROME (EPOGEN<sup>®</sup>, PROCIT<sup>®</sup>, RETACRIT<sup>®</sup> ONLY):**

- CURRENT hemoglobin level < 10 g/dL

**HEPATITIS C WITH CURRENT INTERFERON TREATMENT (EPOGEN<sup>®</sup>, PROCIT<sup>®</sup>, RETACRIT<sup>®</sup> ONLY):**

- Beginning hemoglobin level < 10 g/dL
- **RENEWAL:** CURRENT hemoglobin level < 12 g/dL

**JESDUVROQ<sup>®</sup> (DAPRODUSTAT)**

**Initial**

- Patient is ≥18 years of age; **AND**
- Diagnosis of anemia due to chronic kidney disease (CKD); **AND**
- Patient has been receiving dialysis for ≥4 months; **AND**
- Prescribed by or in consultation with a nephrologist or hematologist; **AND**
- Recent documentation (within 30 days of request) of ALL the following:
  - Patient is currently receiving an erythropoiesis-stimulating agent AND transitioning to Jesduvroq; **AND**
  - Patient has a hemoglobin level ≤ 12.0 g/dL; **OR**
  - Patient is NOT currently receiving an erythropoiesis-stimulating agent; **AND**
  - Patient has a baseline (prior to initiation of Jesduvroq) hemoglobin level < 11 g/dL; **AND**
  - Serum ferritin > 100 ng/mL (mcg/L); **AND**
  - Transferrin saturation (TSAT) >20%
- Length of approval: 6 months

**Renewal**

- Patient must continue to meet the above criteria; **AND**
- Patient has experienced an increase in Hb from baseline; **AND**
- Hemoglobin is < 12 g/dL
- Length of approval: 1 year

## **VAFSEO® (VADADUSTAT)**

### **Initial**

- Patient is 18 years of age or older; **AND**
- Diagnosis of anemia due to chronic kidney disease (CKD); **AND**
- Patient has been receiving dialysis for  $\geq 3$  months; **AND**
- Prescribed by or in consultation with a nephrologist or hematologist; **AND**
- Recent documentation (within 30 days of request) of ALL the following:
  - Patient is currently receiving an erythropoiesis-stimulating agent **AND** transitioning to Vafseo; **AND**
  - Patient has a hemoglobin level  $\leq 12.0$  g/dL; **OR**
  - Patient is **NOT** currently receiving an erythropoiesis-stimulating agent; **AND**
  - Patient has a baseline (prior to initiation of Vafseo) hemoglobin level  $< 11$  g/dL; **AND**
  - Serum ferritin  $> 100$  ng/mL (mcg/L); **AND**
  - Transferrin saturation (TSAT)  $> 20\%$
- Length of approval: 6 months

### **Renewal**

- Patient must continue to meet the above criteria; **AND**
  - Patient has experienced an increase in Hb from baseline; **AND**
  - Hemoglobin is  $< 12$  g/dL
- Length of approval: 1 year

- Duration of Approval:** For the duration of the prescription up to 6 months, unless otherwise noted in Medication/Diagnoses-Specific Information

## HYFTOR / SIROLIMUS

**Drug Class:** mTOR (mammalian target of rapamycin) inhibitor immunosuppressant

**FDA-approved uses:** Indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients  $\geq 6$  years old

**Available dosage forms:** Available in 10-gram tubes as 2 mg per gram (0.2%) topical gel.

### **Coverage Criteria/Limitations for initial authorization:**

- Patient is  $\geq 6$  years old; **AND**
- Patient has a documented diagnosis of facial angiofibroma associated with tuberous sclerosis  
**AND**
- Prescribed by, or in consultation with, either a dermatologist or neurologist
- Length of approval:
  - Initial Authorization: 3 months
  - Continuation of therapy: 1 year
- Route of Administration:** Topical
- Quantity:**
  - Ages 6-11 years: Up to 2 tubes (20 grams) per 30 days
  - Age 12 years and older: Up to 3 tubes (30 grams) per 30 days

### **Criteria for continuation of therapy**

- Documentation Requirements** (e.g., Labs, Medical Record, Special Studies):
  - Prescriber attests to positive symptom improvement based on size and redness of facial angiofibroma

## IMMUNOMODULATORS

### Drug Class:

- Agents to Treat Allergic Fungal Rhinosinusitis (AFRS)
- Agents to Treat Asthma
- Agents to Treat Atopic Dermatitis
- Agents to Treat Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria
- Agents to Treat Chronic Obstructive Pulmonary Disease (COPD)
- Agents to Treat Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
- Agents to Treat Eosinophilic Esophagitis (EoE)
- Agents to Treat Eosinophilic Granulomatosis with Polyangiitis (EGPA)
- Agents to Treat Hypereosinophilic Syndrome (HES)
- Agents to Treat IgE-Mediated Food Allergy
- Agents to Treat Nonsegmental Vitiligo
- Agents to Treat Prurigo Nodularis (PN)

### Biologic Immunomodulators:

- Agents to Treat Ankylosing Spondylitis
- Agents to Treat Crohn's Disease
- Agents to Treat Giant Cell Arteritis (GCA)
- Agents to Treat Hidradenitis Suppurativa
- Agents to Treat Juvenile Idiopathic Arthritis
- Agents to Treat Non-radiographic Axial Spondyloarthritis
- Agents to Treat Plaque Psoriasis
- Agents to Treat Psoriatic Arthritis
- Agents to Treat Rheumatoid Arthritis
- Agents to Treat Ulcerative Colitis
- Agents to Treat Uveitis

## ❖ AGENTS TO TREAT ALLERGIC FUNGAL RHINOSINUSITIS (AFRS)

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®

Clinical PA Criteria for Allergic Fungal Rhinosinusitis (AFRS) Indication:

### **DUPIXENT® (DUPILUMAB):**

- Diagnosis of allergic fungal rhinosinusitis (AFRS); **AND**
- Patient is 6 years of age or older; **AND**
- Prescribed by or consultation with an allergist, immunologist, or pulmonologist; **AND**
- Patient has had sino-nasal surgery.

Non-Preferred Agents: *Clinical Prior Authorization below*

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**Duration of Approval:** 1 year

❖ **AGENTS TO TREAT ASTHMA**

**Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®  
Fasenra® pen  
Xolair® syringes, autoinjectors

**Clinical PA Criteria for Asthma Indications:**

- Patient's asthma symptoms have not been adequately controlled by at least three months of an asthma treatment regimen that must include an inhaled corticosteroid; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

**DUPIXENT® (DUPILUMAB):**

- Note:
  - A 56-day supply will be allowed for patients requiring dosing once every 28 days (every 4 weeks)
  - The pre-filled PEN is for use in adult and pediatric patients aged 2 years and older.
  - The pre-filled SYRINGE is for use in adult and pediatric patients aged 6 months and older.
- **Patient must have moderate to severe asthma diagnosed as ONE of the following types:**
  - Asthma with eosinophilic phenotype with eosinophil count  $\geq$  150 cells/mcL; **OR**
  - Oral corticosteroid dependent asthma with at least 1 month of daily oral corticosteroid use within the last 3 months; **AND**
  - Patient must be 6 years of age or older

**FASENRA® (BENRALIZUMAB):**

- **Patient must have severe asthma; AND**

- Eosinophil blood count of  $\geq 150$  cells/ $\mu\text{L}$  within last 6 weeks or  $\geq 300$  cells/ $\mu\text{L}$  within the last 12 months; **AND**
- Patient must be 6 years of age or older

**XOLAIR® (OMALIZUMAB)**

- **Moderate to severe persistent asthma; AND**
  - Patient is 6 years of age or older; **AND**
  - Patient has a positive skin test or in vitro testing (RAST, etc.) for allergen specific IgE antibodies for one or more seasonal aeroallergens; **AND**
  - Baseline IgE level is  $\geq 30$  IU/ml

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Nucala® syringe, auto-injector  
Tezspire® pen

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**NUCALA® (MEPOLIZUMAB):**

- **Patient must have severe asthma; AND**
  - Eosinophil blood count of  $\geq 150$  cells/ $\mu\text{L}$  within last 6 weeks or  $\geq 300$  cells/ $\mu\text{L}$  within the last 12 months; **AND**
  - Patient must be 6 years of age or older; **AND**
  - For Nucala 40mg/0.4 ml, patient age must be  $\leq 11$  years of age

**TEZSPIRE® (TEZPELUMAB-EKKO)**

- **Patient must have severe asthma; AND**
  - Patient is 12 years of age or older; **AND**
  - Patient has been trained to self-administer this product; **AND**
  - Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Tezspire; **AND**
  - Bypass PDL criteria if patient does not meet specific criteria for Preferred agents (e.g. eosinophil blood count and/or IgE blood level requirements)

**Duration of Approval:** 1 year

## ❖ AGENTS TO TREAT ATOPIC DERMATITIS

**Preferred Agents:** *Clinical Prior Authorization below*

|           |                                   |
|-----------|-----------------------------------|
| Adbry®    | pimecrolimus (generic for Elidel) |
| Dupixent® | tacrolimus                        |
| Eucrisa®  |                                   |

### **Clinical PA Criteria For Atopic Dermatitis Indications For Each Agent**

- **Diagnosis of atopic dermatitis**
  - **Dupixent®:** moderate to severe for ages  $\geq$  6 months (see additional medication specific criteria below)
  - **Eucrisa®:** mild to moderate for ages  $\geq$  3 months
  - **pimecrolimus (generic for Elidel®):** mild to moderate for ages  $\geq$  2 years
  - **Tacrolimus 0.03%:** moderate to severe for ages  $\geq$  2 years
  - **Tacrolimus 0.1%:** moderate to severe for ages  $\geq$  16 years
  - **See additional medication-specific criteria below:**

### **DUPIXENT® (DUPILUMAB)**

- Note:
  - A 56-day supply will be allowed for patients requiring dosing once every 28 days (every 4 weeks)
  - The pre-filled PEN is for use in adult and pediatric patients aged 2 years and older.
  - The pre-filled SYRINGE is for use in adult and pediatric patients aged 6 months and older.

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|           |           |
|-----------|-----------|
| Cibinqo®  | Opzelura® |
| Ebglyss®  | Rinvoq®   |
| Nemluvio® |           |

## ❖ AGENTS TO TREAT ATOPIC DERMATITIS, continued

### **Non-Preferred Agent PA Criteria:**

- **Diagnosis of atopic dermatitis**
- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication
- Additional disease severity and age limits:

- **Rinvoq®**: moderate to severe for ages ≥ 12 years
- **See additional medication-specific criteria below:**

**ADBRY® (TRALOKINUMAB-LDRM)**

- **Diagnosis of moderate to severe atopic dermatitis; AND**
  - Patient age ≥ 12 years old; **AND**
  - **Adbry 150mg:**
    - Quantity limit: 4 syringes per 28 days (with special allowance for initial dose);
    - OR**
  - **Adbry 300mg:**
    - Quantity limit: 2 Autoinjectors per 28 days (with special allowance for initial dose)

**CIBINQO® (ABROCITINIB)**

- **Diagnosis of moderate to severe atopic dermatitis; AND**
  - Patient age ≥ 12 years old

**EBGLYSS® (LEBRIKIZUMAB-LBKZ)**

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient is 12 years of age or older; **AND**
- Patient weighs at least 40 kg (88 lbs)
- Quantity Limit: 1 pen (2mL) per 28-day days (special allowance for initial and subsequent induction fills)
- Length of approval: 6 months

**NEMLUVIO (NEMOLIZUMAB-ILTO)**

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient is 12 years of age or older
- Quantity Limit: 1 pen (30mg) per 28 days (special allowance of 2 pens for loading dose)
- Length of approval: 6 months

**Renewal**

- Documentation submitted demonstrating a positive response to therapy.
  - Prescriber attests the patient has achieved clear or almost clear skin, and in accordance with the product label, the patient will be transitioned to a dosage of 1 pen (30 mg) every 8 weeks. *NOTE: renewal PA will limit dosage accordingly;* **OR**
  - Prescriber attests the patient has not achieved clear or almost clear skin yet but has had a positive response to therapy. Prescriber is requesting continuation of dosage of 1 pen (30 mg) every 4 weeks.

**OPZELURA® (RUXOLITINIB PHOSPHATE)**

- **Diagnosis of mild to moderate atopic dermatitis; AND**

- Patient has atopic dermatitis estimated to affect ≤ 20% of the body surface area; **AND**
- Patient age ≥ 2 years old;

**QUANTITY LIMITS**

|  |  |
|--|--|
| Adbry® (tralokinumab-ldrm) 150mg syringes      | 4 syringes per 28 days (with special allowance for initial dose)                           |
| Adbry® (tralokinumab-ldrm) 300mg Autoinjectors | 2 autoinjectors per 28 days (with special allowance for initial dose)                      |
| Ebglyss (lebrikizumab-lbkz) pen/syringe        | 1 pen (2mL) per 28-day days (special allowance for initial and subsequent induction fills) |
| Eucrisa® (crisaborole)                         | 100 gm per 30 days   |
| Nemluvio (nemolizumab-ilto) pen                | 1 pen (30mg) per 28 days (special allowance of 2 pens for loading dose)                    |
| Opzelura® (ruxolitinib phosphate)              | 240gm (4 x 60gm) per 30 days   |
| pimecrolimus (generic for Elidel®)             | 30gm per 30 days   |
| Tacrolimus                                     | 30gm per 30 days   |

- ☐ **Duration of Approval:** 6 months for **FDA approved diagnosis** noted above, unless otherwise noted in Medication/Diagnosis-Specific Criteria

**❖ AGENTS TO TREAT CHRONIC IDIOPATHIC URTICARIA / CHRONIC SPONTANEOUS URTICARIA**

**Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®  
Xolair® syringes, autoinjectors

**Clinical PA Criteria for Chronic Idiopathic Urticaria Indications:**

**DUPIXENT® (DUPILUMAB):**

- **Diagnosis of Chronic Spontaneous Urticaria (CSU)/Chronic Idiopathic Urticaria; AND**
  - Patient is 12 years of age or older; **AND**
  - Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
  - Patient has had urticaria for at least 6 weeks with symptoms present despite an adherent trial of at least 2 weeks duration of an H1-antihistamine.

**XOLAIR® (OMALIZUMAB)**

- **Diagnosis of Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CSU); AND**
  - Patient is 12 years of age or older; **AND**
  - Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
  - Patient has had urticaria for at least 6 weeks with symptoms present despite an adherent trial of at least 2 weeks duration of an H1-antihistamine

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Rhapsido®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication
- **See additional medication-specific criteria below:**

**RHAPSIO® (REMIBRUTINIB)**

- Diagnosis of Chronic Spontaneous Urticaria (CSU); **AND**
- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or dermatologist; **AND**
- Patient has had urticaria for at least 6 weeks with symptoms present despite an adherent trial of at least 2 weeks duration of an H1-antihistamine.

**Duration of Approval:** 1 year

❖ **AGENTS TO TREAT CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)**

**Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®

❖ **AGENTS TO TREAT CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), continued**

**Clinical PA Criteria for Chronic Obstructive Pulmonary Disease (COPD):**

### **DUPIXENT® (DUPILIMAB)**

- **Diagnosis of inadequately controlled chronic obstructive pulmonary disease (COPD); AND**
  - Patient has had an eosinophilic count  $\geq 300$  cells/mcL; **AND**
  - Patient  $\geq 18$  years old; **AND**
  - Patient is concurrently treated with triple therapy with inhaled corticosteroid [ICS], long-acting beta-2 agonist [LABA], and long-acting muscarinic antagonist [LAMA]; **OR**
  - Patient is concurrently treated with a LABA and LAMA if ICS therapy is contraindicated.

#### **Non-Preferred Agents:** *Prior Authorization Criteria below*

Nucala®

#### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication
- **See additional medication-specific criteria below:**

### **NUCALA® (MEPOLIZUMAB)**

- **Diagnosis of inadequately controlled chronic obstructive pulmonary disease (COPD); AND**
  - Patient has had an eosinophilic count  $\geq 300$  cells/mcL; AND
  - Patient  $\geq 18$  years old; AND
  - Patient is concurrently treated with triple therapy with inhaled corticosteroid [ICS], long-acting beta-2 agonist [LABA], and long-acting muscarinic antagonist [LAMA]; **OR**
  - Patient is concurrently treated with a LABA and LAMA if ICS therapy is contraindicated.

**Duration of Approval:** 1 year

## **❖ AGENTS TO TREAT CHRONIC RHINOSINUSITIS WITH NASAL POLYPOSIS (CRSWNP)**

#### **Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®  
Xolair® syringes, autoinjectors

**Clinical PA Criteria for chronic rhinosinusitis with nasal polyposis (CRSwNP) Indications:**

**DUPIXENT® (DUPILUMAB):**

- **Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
  - Patient ≥ 12 years old; **AND**
  - Patient has inadequate response after 3 consistent months use of intranasal steroids or oral corticosteroids; **AND**
  - Patient is concurrently treated with intranasal corticosteroids

**XOLAIR® (OMALIZUMAB)**

- **Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
  - Patient is 18 years of age or older; **AND**
  - Prescribed by or in consultation with an allergist, immunologist or otolaryngologist; **AND**
  - Patient has not been adequately controlled by at least three months of treatment with an intranasal steroids or oral corticosteroids; **AND**
  - Baseline IgE level is ≥ 30 IU/ml; **AND**
  - Patient is concurrently treated with intranasal corticosteroids

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication
- **See additional medication-specific criteria below:**

**NUCALA (MEPOLIZUMAB)**

- **Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
  - Patient ≥ 18 years old **AND**
  - Patient has inadequate response after 3 consistent months use of intranasal steroids or oral corticosteroids; **AND**
  - Patient is concurrently treated with intranasal corticosteroids

**Duration of Approval:** 1 year

## ❖ AGENTS TO TREAT EOSINOPHILIC ESOPHAGITIS (EOE)

**Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®

**Clinical PA Criteria for eosinophilic esophagitis (EoE):**

**DUPIXENT® (DUPILUMAB):**

- **Diagnosis of eosinophilic esophagitis (EoE); AND**
  - Patient ≥1 years old; **AND**
  - Patient weighs ≥ 15 kg; **AND**
  - Prescribed by or consultation with an allergist or gastroenterologist; **AND**
  - Patient did not respond clinically to treatment with a topical glucocorticosteroid or proton pump inhibitor

❑ **Duration of Approval:** 1 year

## ❖ AGENTS TO TREAT EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

**Preferred Agents:** *Clinical Prior Authorization below*

Fasenra®

**Clinical PA Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA)**

**FASENRA® (BENRALIZUMAB)**

- **Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA); AND**
  - Patient is 18 years of age or older

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication
- **See additional medication-specific criteria below:**

**NUCALA® (MEPOLIZUMAB):**

- **Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA); AND**
  - Patient is 18 years of age or older

**Duration of Approval:** 1 year

❖ **AGENTS TO TREAT HYPEREOSINOPHILIC SYNDROME (HES)**

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

**Non-Preferred Agent PA Criteria:**

**NUCALA® (MEPOLIZUMAB):**

- **Diagnosis of hypereosinophilic syndrome (HES); AND**
  - Patient is 12 years of age or older
  - Bypass PDL criteria of a failure with a preferred agent when the non-preferred product has a unique FDA approved indication.

**Duration of Approval:** 1 year

❖ **AGENTS TO TREAT IGE-MEDIATED FOOD ALLERGY**

**Preferred Agents:** *Clinical Prior Authorization below*

Xolair

**Clinical PA Criteria for IgE-Mediated Food Allergy**

**XOLAIR® (OMALIZUMAB)**

- **Diagnosis of IgE-mediated food allergy; AND**
  - Patient is 1 year of age or older; **AND**
  - Prescribed by or in consultation with an allergist or immunologist; **AND**
  - Patient will follow food allergen avoidance in conjunction with Xolair; **AND**
  - Baseline IgE level is  $\geq 30$  IU/ml

**Duration of Approval:** 1 year

## ❖ AGENTS TO TREAT NONSEGMENTAL VITILIGO

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Opzelura®

**Non-Preferred Agent PA Criteria:**

**OPZELURA® (RUXOLITINIB PHOSPHATE)**

- **Diagnosis of nonsegmental vitiligo; AND**
  - Patient has vitiligo involvement estimated to affect ≤ 10% of the body surface area; **AND**
  - Patient is ≥12 years old; **AND**
  - Prescribed by or in consultation with a dermatologist
  - Bypass PDL criteria of a failure with a preferred agent when the non-preferred product has a unique FDA approved indication.

**Duration of Approval:** 1 year

## ❖ AGENTS TO TREAT PRURIGO NODULARIS (PN)

**Preferred Agents:** *Clinical Prior Authorization below*

Dupixent®

**Clinical PA Criteria for Prurigo Nodularis (PN):**

**DUPIXENT® (DUPILUMAB):**

- **Diagnosis of prurigo nodularis (PN); AND**
  - Patient ≥18 years old; **AND**
  - Prescribed by or in consultation with a dermatologist, allergist, or immunologist

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Nemluvio®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication; **OR**
- Contraindication or drug to drug interaction with one preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial with the preferred medication

- See additional medication-specific criteria below:

**NEMLUVIO® (NEMOLIZUMAB-ILTO):**

- **Diagnosis for prurigo nodularis; AND**
- Patient is 18 years of age or older; **AND**
- Prescribed by or in consultation with a dermatologist, allergist or immunologist
- Quantity Limit: 1 pen (30mg) per 28 days (special allowance of 2 pens for loading dose and patients weighing  $\geq 90$  kg)

- ☐ **Duration of Approval:** 1 year

## **BIOLOGIC IMMUNOMODULATORS**

### **❖ AGENTS TO TREAT ANKYLOSING SPONDYLITIS**

**Preferred Agents:** *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)  
Cosentyx®  
Enbrel®  
Humira®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                             |                         |
|-----------------------------|-------------------------|
| Abrilada®                   | Cimzia®, Cimzia Kit®    |
| adalimumab-aacf (unbranded) | Cyltezo®                |
| Idacio)                     | Hadlima®                |
| adalimumab-aaty (unbranded) | Hulio®                  |
| Yuflyma)                    | Hyrimoz®                |
| adalimumab-adaz (unbranded) | Idacio®                 |
| Hyrimoz)                    | Rinvoq®                 |
| adalimumab-fkjp (unbranded) | Simlandi®               |
| Hulio)                      | Simponi®, Simponi ARIA® |
| adalimumab-ryvk (unbranded) | Taltz®                  |
| Simlandi)                   | Xeljanz®, Xeljanz XR®   |
| Amjevita®                   | Yuflyma®                |
| Bimzelx®                    | Yusimry®                |

### **❖ AGENTS TO TREAT CROHN'S DISEASE**

**Preferred Agents:** *No prior authorization except select Preferred biosimilars for Stelara – see criteria below*

adalimumab-adbm (unbranded Cyltezo)  
Humira®  
Pyzchiva®  
Steqeyma®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                             |                             |
|-----------------------------|-----------------------------|
| Abrilada®                   | adalimumab-adaz (unbranded) |
| adalimumab-aacf (unbranded) | Hyrimoz)adalimumab-fkjp     |
| Idacio) adalimumab-aaty     | (unbranded Hulio)           |
| (unbranded Yuflyma)         |                             |

adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Cimzia®, Cimzia Kit®  
Cyltezo®  
Entyvio®  
Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Imuldosa®  
Omvoh®  
Otulfi®  
Selarsdi®  
Rinvoq®  
Simlandi®

Skyrizi®  
Starjemza® (Ustekinumab-  
HMNY)  
Stelara®  
Tremfya®  
ustekinumab-aaaz (unbranded  
Otulfi)  
ustekinumab-aekn (unbranded  
Selarsdi)  
ustekinumab-ttwe (unbranded  
Pyzchiva)  
Yesintek®  
Yuflyma®  
Yusimry®  
Zymfentra® pen/syringe

#### ❖ AGENTS TO TREAT GIANT CELL ARTERITIS (GCA)

**Preferred Agents:** *No Prior Authorization required*

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Actemra®  
Rinvoq®  
Tyenne®

#### ❖ AGENTS TO TREAT HIDRADENITIS SUPPURATIVA

**Preferred Agents:** *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)  
Cosentyx®  
Humira®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
adalimumab-aacf (unbranded  
Idacio)

adalimumab-aaty (unbranded  
Yuflyma)  
adalimumab-adaz (unbranded  
Hyrimoz)

adalimumab-fkjp (unbranded  
Hulio)  
adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Bimzelx®  
Cyltezo®

Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Simlandi®  
Yuflyma®  
Yusimry®

## ❖ AGENTS TO TREAT JUVENILE IDIOPATHIC ARTHRITIS

**Preferred Agents:** *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)  
Enbrel®  
Humira®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
Actemra® SC  
adalimumab-aacf (unbranded  
Idacio)  
adalimumab-aaty (unbranded  
Yuflyma)  
adalimumab-adaz (unbranded  
Hyrimoz)  
adalimumab-fkjp (unbranded  
Hulio)  
adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Cimzia®, Cimzia Kit®  
Yusimry®

Cyltezo®  
Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Kevzara®  
Orencia® SC  
Rinvoq®  
Rinvoq LQ®  
Simlandi®  
Simponi ARIA®  
Tyenne®  
Xeljanz® tabs, solution  
Yuflyma®

## ❖ AGENTS TO TREAT NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

**Preferred Agents:** *No Prior Authorization required*

Cosentyx®

## ❖ AGENTS TO TREAT NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS, continued

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Cimzia®, Cimzia Kit®  
Bimzelx®  
Rinvoq®  
Taltz®

## ❖ AGENTS TO TREAT PLAQUE PSORIASIS

**Preferred Agents:** *No prior authorization except select Preferred biosimilars for Stelara – see criteria below*

adalimumab-adbm (unbranded Cyltezo)  
Cosentyx®  
Enbrel®  
Humira®  
Pyzchiva®  
Steqeyma®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
adalimumab-aacf (unbranded Idacio)  
adalimumab-aaty (unbranded Yuflyma)  
adalimumab-adaz (unbranded Hyrimoz)  
adalimumab-fkjp (unbranded Hulio)  
adalimumab-ryvk (unbranded Simlandi)  
Amjevita®  
Bimzelx®  
Cimzia®, Cimzia Kit®  
Cyltezo®  
Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Imuldosa®  
Ilumya®

Otezla® / Otezla XR®  
Otulfi®  
Selarsdi®  
Simlandi®  
Skyrizi®  
Sotyktu®  
Starjemza® (Ustekinumab-HMNY)  
Stelara®  
Taltz®  
Tremfya®  
ustekinumab-aaaz (unbranded Otulfi)  
ustekinumab-aekn (unbranded Selarsdi)  
ustekinumab-ttwe (unbranded Pyzchiva)  
Yesintek®  
Yuflyma®  
Yusimry®

## ❖ AGENTS TO TREAT PSORIATIC ARTHRITIS

**Preferred Agents:** *No prior authorization except select Preferred biosimilars for Stelara – see criteria below*

adalimumab-adbm (unbranded  
Cyltezo)  
Cosentyx®  
Enbrel®

Humira®  
Pyzchiva®  
Steqeyma®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
adalimumab-aacf (unbranded  
Idacio)  
adalimumab-aaty (unbranded  
Yuflyma)  
adalimumab-adaz (unbranded  
Hyrimoz)  
adalimumab-fkjp (unbranded  
Hulio)  
adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Bimzelx®  
Cimzia®, Cimzia Kit®  
Cyltezo®  
Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Imuldosa®  
Orencia® SC  
Otezla® / Otezla XR®  
Otulfi®

Selarsdi®  
Rinvoq®  
Rinvoq LQ®  
Simlandi®  
Simponi®, Simponi ARIA®  
Skyrizi®  
Sotyktu®  
Starjemza® (Ustekinumab-  
HMNY)  
Stelara®  
Taltz®  
Tremfya®  
ustekinumab-aaaz (unbranded  
Otulfi)  
ustekinumab-aekn (unbranded  
Selarsdi)  
ustekinumab-ttwe (unbranded  
Pyzchiva)  
Xeljanz®, Xeljanz XR®  
Yesintek®  
Yuflyma®  
Yusimry®

## ❖ AGENTS TO TREAT RHEUMATOID ARTHRITIS

**Preferred Agents:** *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)  
Enbrel®  
Humira®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
Actemra® SC

adalimumab-aacf (unbranded  
Idacio)

adalimumab-aaty (unbranded  
Yuflyma)  
adalimumab-adaz (unbranded  
Hyrimoz)  
adalimumab-fkjp (unbranded  
Hulio)

adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Cimzia®, Cimzia Kit®  
Cyltezo®

#### ❖ AGENTS TO TREAT RHEUMATOID ARTHRITIS, continued

Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Kevzara®  
Kineret®  
Olumiant®  
Yusimry®

Orencia® SC  
Rinvoq®  
Simlandi®  
Simponi®, Simponi ARIA®  
Tyenne®  
Xeljanz®, Xeljanz XR®  
Yuflyma®

#### ❖ AGENTS TO TREAT ULCERATIVE COLITIS

**Preferred Agents:** *No prior authorization except select Preferred biosimilars for Stelara – see criteria below*

adalimumab-adbm (unbranded Cyltezo)  
Humira®  
Pyzchiva®  
Steqeyma®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
adalimumab-aacf (unbranded  
Idacio)  
adalimumab-aaty (unbranded  
Yuflyma)  
adalimumab-adaz (unbranded  
Hyrimoz)  
adalimumab-fkjp (unbranded  
Hulio)

adalimumab-ryvk (unbranded  
Simlandi)  
Amjevita®  
Cyltezo®  
Entyvio®  
Hadlima®  
Hulio®  
Hyrimoz®  
Idacio®  
Imuldosa®

OmvoH®  
 Otulfi®  
 Selarsdi®  
 Rinvoq®  
 Simlandi®  
 Simponi®  
 Skyrizi®  
 Stelara®  
 Starjemza® (Ustekinumab-  
 HMNY)  
 Tremfya®  
 ustekinumab-aaaz (unbranded  
 Otulfi)

ustekinumab-aekn (unbranded  
 Selarsdi)  
 ustekinumab-ttwe (unbranded  
 Pyzchiva)  
 Velsipity®  
 Xeljanz®, Xeljanz XR®  
 Yesintek®  
 Yuflyma®  
 Yusimry®  
 Zeposia®  
 Zymfentra® pen/syringe

## ❖ AGENTS TO TREAT UVEITIS

### **Preferred Agents:** *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)  
 Humira®

### **Non-Preferred Agents:** *Prior Authorization Criteria below*

Abrilada®  
 adalimumab-aacf (unbranded  
 Idacio)  
 adalimumab-aaty (unbranded  
 Yuflyma)  
 adalimumab-adaz (unbranded  
 Hyrimoz)  
 adalimumab-fkjp (unbranded  
 Hulio)  
 adalimumab-ryvk (unbranded  
 Simlandi)

Amjevita®  
 Cyltezo®  
 Hadlima®  
 Hulio®  
 Hyrimoz®  
 Idacio®  
 Simlandi®  
 Yuflyma®  
 Yusimry®

### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- The patient's condition is clinically stable at this time, so that switching medications would cause deterioration in their condition; **OR**
- Therapeutic failure with one preferred medication in the same subclass
- Bypass PDL criteria of failure with a preferred agent in cases when the non-preferred product has a unique FDA approved indication.
- **See additional medication-specific criteria below:**

**ABRILADA® (ADALIMUMAB-AFZB)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurative: **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**ACTEMRA® (TOCILIZUMAB)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of active polyarticular juvenile idiopathic arthritis; **OR**
  - Diagnosis of active systemic juvenile idiopathic arthritis; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of giant cell arteritis; **OR**
  - Diagnosis of systemic sclerosis-associated interstitial lung disease

**AMJEVITA® (ADALIMUMAB-ATTO)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**BIMZELX® (BIMEKIZUMAB-BKZX)**

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of active psoriatic arthritis (PsA); **OR**
- Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; **OR**
- Diagnosis of active ankylosing spondylitis (AS); **OR**
- Diagnosis of moderate-to-severe hidradenitis suppurativa (HS); **AND**

- Patient must be 18 years or older

#### **CYLTEZO® (ADALIMIMAB-ADBIM)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn’s disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

#### **ENTYVIO® (VEDOLIZUMAB)**

- Diagnosis of Crohn’s disease; **OR**
- Diagnosis of ulcerative colitis; **AND**
- Patient must be 18 years or older; **AND**
- Trial and failure on one medication from **each** of the following classes:
  - Aminosalicylate [i.e., mesalamine (Pentasa®, Lialda®, Delzicol®), olsalazine (Dipentum®), balsalazide (Colazal®, sulfasalazine (Azulfidine®))]
  - Oral steroid
  - Thiopurine [i.e., azathioprine (Imuran®), mercaptopurine (Purinethol®)]
  - TNF (tumor necrosis factor) blocker [i.e., infliximab (Remicade®), adalimumab (Humira®)]
  - **Length of authorization:** Initial approval = 14 weeks; renewal = 1 year

#### **HADLIMA® (ADALIMUMAB-BWWD)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn’s disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**HULIO® (ADALIMUMAB-FKJP)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**HYRIMOZ® (ADALIMUMAB-ADAZ)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**IDACIO® (ADALIMUMAB-AACF)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**ILUMYA® (TILDRAKIZUMAB)**

- Diagnosis of moderate to severe plaque psoriasis; **AND**
- Patient must be 18 years or older

**IMULDOSA® (USTEKINUMAB-SRLF)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**KEVZARA® (SARILUMAB) – PDL CRITERIA DO NOT APPLY FOR POLYMYALGIA RHEUMATICA**

- Patient must be 18 years or older; **AND**
  - Diagnosis of Polymyalgia Rheumatica (PMR); **OR**
  - Diagnosis of moderately to severely active rheumatoid arthritis (RA); **OR**
- Patient weight is 63 kg or greater; **AND**
  - Diagnosis of polyarticular juvenile idiopathic arthritis

**OLUMIANT® (BARICITINIB) – PDL CRITERIA DO NOT APPLY FOR ALOPECIA AREATA**

- Diagnosis of moderate to severe rheumatoid arthritis; **OR**
- Diagnosis of severe alopecia areata; **AND**
  - Patient must be 18 years or older

**OMVOH**

- Diagnosis of moderately to severely active ulcerative colitis (UC); **OR**
- Diagnosis of moderately to severely active Crohn's disease; **AND**
- Patient must be 18 years or older; **AND**
- Prescribed by or in consultation with a gastroenterologist

**OTEZLA® / OTEZLA XR® (APREMILAST)**

- Patient must be 6 years or older; **AND**
  - Diagnosis of active psoriatic arthritis; **OR**
  - Diagnosis of plaque psoriasis; **OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of active psoriatic arthritis ; **OR**
  - Diagnosis of plaque psoriasis; **OR**
  - Diagnosis of oral ulcers associated with Behcet's Disease; **AND**
- Must be prescribed by or in consultation with a rheumatologist or dermatologist

- OTEZLA is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 20 kg
- OTEZLA XR is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 50 kg

**OTULFI® (USTEKINUMAB-AAUZ)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn’s disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**PYZCHIVA® (USTEKINUMAB-TTWE)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Trial/failure of preferred Tumor Necrosis Factor (TNF) Blocker; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn’s disease or ulcerative colitis; **AND**
  - Trial/failure of preferred Tumor Necrosis Factor (TNF) Blocker; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks

**RINVOQ® (UPADACITINIB)**

- Patient must be 2 years or older; **AND**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of polyarticular juvenile idiopathic arthritis; **OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA); **OR**
  - Diagnosis of giant cell arteritis; **OR**
  - Diagnosis of moderately to severely active Crohn’s disease; **OR**
  - Diagnosis of moderately to severely active ulcerative colitis

**RINVOQ LQ® (UPADACITINIB)**

- Patient must be 2 years or older; **AND**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of polyarticular juvenile idiopathic arthritis;

**SELARSDI® (USTEKINUMAB-AEKN)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**SIMLANDI® (ADALIMUMAB-RYVK)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**SKYRIZI® (RISANKIZUMAB)**

- Patient is 18 years of age or older; **AND**
- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of active psoriatic arthritis; **AND**
  - Prescribed by or in consultation with a dermatologist or rheumatologist; **OR**
- Diagnosis of Crohn's disease; **OR**
- Diagnosis of ulcerative colitis; **AND**
  - Prescribed by or in consultation with a gastroenterologist or rheumatologist

**SOTYKTU® (DEUCRAVACITINIB)**

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of active psoriatic arthritis; **AND**
  - Patient ≥18 years of age: **AND**
  - Must be prescribed by or in consultation with a dermatologist or rheumatologist; **AND**
  - Quantity Limit: 1 per day

**STARJEMZA® (USTEKINUMAB-HMNY)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**STELARA® (USTEKINUMAB)**

- Diagnosis of psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**STEQEYMA (USTEKINUMAB-STBA)**

- Diagnosis of psoriasis or psoriatic arthritis; **AND**
  - Trial/failure of preferred Tumor Necrosis Factor (TNF) Blocker; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Trial/failure of preferred Tumor Necrosis Factor (TNF) Blocker; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks

**TALTZ® (IXEKIZUMAB)**

- Patient must be 6 years of age or older with a diagnosis of moderate to severe plaque psoriasis; **OR**
- Patient must be 18 years or older; **AND**
- Diagnosis of psoriatic arthritis; **OR**
- Diagnosis of active ankylosing spondylitis; **OR**
- Diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA); **AND**
- Must be prescribed by a rheumatologist or dermatologist or asthma/allergy specialist

**TREMFYA® (GUSELKUMAB)**

- Patient is 6 years of age and older and weighs at least 40kg; **AND**
  - Diagnosis of moderate to severe plaque psoriasis (PSO); **OR**
  - Diagnosis of psoriatic arthritis (PsA); **OR**
- Patient is 18 years or older; **AND**
  - Diagnosis of moderately to severely active ulcerative colitis (UC); **OR**
  - Diagnosis of moderately to severely active Crohn's disease.

**TYENNE® (TOCILIZUMAB-AAZG)**

- Patient is 2 years of older; **AND**
  - Diagnosis of active polyarticular juvenile idiopathic arthritis; **OR**
  - Diagnosis of active systemic juvenile idiopathic arthritis; **OR**
- Patient is 18 years or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of giant cell arteritis

**UNBRANDED PYZCHIVA® (USTEKINUMAB-TTWE)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**UNBRANDED OTULFI® (USTEKINUMAB-AAUZ)**

- Diagnosis of plaque psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4; **OR**
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

**VELSIPITY® (ETRASIMOD ARGININE)**

- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Patient must be 18 years or older; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**

- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, has been performed before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months.

#### **YESINTEK (USTEKINUMAB-STBA)**

- Diagnosis of psoriasis or psoriatic arthritis; **AND**
  - Quantity limit:
    - 90 mg every 12 weeks with initial dose Week 0 and 4
- Diagnosis of Crohn's disease or ulcerative colitis; **AND**
  - Quantity limit:
    - 520 mg for initial dose
    - 90 mg every 8 weeks
- Therapeutic failure with one preferred ustekinumab biosimilar to Stelara

#### **XELJANZ® / XELJANZ XR® / XELJANZ® SOLUTION (TOFACITINIB)**

##### **Xeljanz tablets and Xeljanz Solution:**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of polyarticular juvenile idiopathic arthritis (pJIA) (Note: Xeljanz Solution is only approved for pJIA.); **OR**

##### **Xeljanz tablets and Xeljanz XR tablets:**

- Patient is 18 years of age or older; **AND**
  - Diagnosis of rheumatoid arthritis (RA); **OR**
  - Diagnosis of psoriatic arthritis (PsA) **OR**
  - Diagnosis of ankylosing spondylitis (AS); **AND**
  - Must be prescribed by or in consultation with a rheumatologist or dermatologist; **OR**
  - Diagnosis of ulcerative colitis; **AND**
  - Prescribed by or in consultation with a gastroenterologist

#### **YUFLYMA® (ADALIMUMAB-AATY)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn's disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
- Diagnosis of non-infectious intermediate, posterior, or panuveitis

**YUSIMRY® (ADALIMUMAB-AQVH)**

- Patient is 2 years of age or older; **AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis; **OR**
- Patient is 6 years of age or older; **AND**
  - Diagnosis of moderate to severe Crohn’s disease; **OR**
- Patient is 18 years of age or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of psoriatic arthritis; **OR**
  - Diagnosis of ankylosing spondylitis; **OR**
  - Diagnosis of moderate to severe ulcerative colitis; **OR**
  - Diagnosis of moderate to severe plaque psoriasis; **OR**
  - Diagnosis of moderate to severe hidradenitis suppurativa; **OR**
  - Diagnosis of non-infectious intermediate, posterior, or panuveitis

**ZEPOSIA® (OZANIMOD)**

- Patient is 18 years of age or older; **AND**
- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, has been performed before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months

**ZYMFENTRA® (INFLIXIMAB-DYYB)**

- Patient is 18 years of age or older; **AND**
- Diagnosis is moderate to severe Crohn’s disease; **OR**
- Diagnosis of moderate to severe ulcerative colitis; **AND**
- Prescriber attests that the patient has completed an intravenous induction regimen with an infliximab product; **AND**
- Prescribed by or in consultation with a gastroenterologist

**Duration of Approval:** 1 year, unless otherwise noted in Medication-Specific Information

| <b>TABLE 1 – QUANTITY LIMITS (BIOLOGICS)</b>           |                     | <b>5 Pages Total</b> |
|--|---------------------|----------------------|
| <b>Drug Name</b>                                       | <b>Package Size</b> | <b>Limitation *</b>  |
| ABRILADA(CF) 20 MG/0.4 ML SYRINGE                      | 1 each or 2 each    | 2 per 28 days        |
| ABRILADA(CF) 40 MG/0.8 ML SYRINGE                      | 1 each or 2 each    | 4 per 28 days        |
| ABRILADA(CF) PEN 40 MG/0.8 ML                          | 1 or 2 each         | 4 each per 28 days   |
| ABRILADA(CF) PEN 40 MG/0.8 ML (2 PACK)                 | 1 each              | 2 each per 28 days   |
| ACTEMRA 162 MG/0.9 ML SYRINGE                          | 0.9 mL              | 3.6 mL per 28 days   |
| ACTEMRA ACTPEN 162 MG/0.9 ML                           | 0.9 mL              | 3.6 mL per 28 days   |
| ADALIMUMAB-AACF(CF) 40 MG/0.8 ML SYRINGE (2 PACK)      | 1 each              | 2 each per 28 days   |
| ADALIMUMAB-AACF(CF) PEN 40 MG/0.8 ML (2 PACK)          | 1 each              | 2 each per 28 days   |
| ADALIMUMAB-AACF(CF) PEN CRHN-UC-HS 40                  | 3 each              | 3 (1 kit) per year   |
| ADALIMUMAB-AACF(CF) PEN PSO-UV 40 MG/0.8 ML            | 2 each              | 2 (1 kit) per year   |
| ADALIMUMAB-AATY(CF) 20 MG/0.2 ML SYRINGE (2 PACK)      | 1 each              | 1 each per 28 days   |
| ADALIMUMAB-AATY(CF) 40 MG/0.4 ML AUTOINJECTOR          | 1 or 2 each         | 4 each per 28 days   |
| ADALIMUMAB-AATY(CF) 40 MG/0.4 ML AUTOINJECTOR (2 PACK) | 1 each              | 2 each per 28 days   |
| ADALIMUMAB-AATY(CF) 40 MG/0.4 ML SYRINGE (2 PACK)      | 1 each              | 2 each per 28 days   |
| ADALIMUMAB-AATY(CF) 80 MG/0.8 ML AUTOINJECTOR          | 1 or 2 each         | 2 each per 28 days   |
| ADALIMUMAB-AATY(CF) AUTO CD-UC-HS START 80             | 3 each              | 3 (1 kit) per year   |
| ADALIMUMAB-ADAZ(CF) 40 MG SYRG                         | 0.8 mL              | 1.6 mL per 28 days   |
| ADALIMUMAB-ADAZ(CF) PEN 40 MG                          | 0.8 mL              | 1.6 mL per 28 days   |
| ADALIMUMAB-ADAZ(CF) PEN 80 MG/0.8 ML                   | 0.8 mL              | 1.6 mL per 28 days   |
| ADALIMUMAB-ADBM(CF) 40 MG/0.4 ML SYRNG                 | 1 or 2 each         | 4 each per 28 days   |
| ADALIMUMAB-ADBM(CF) 40 MG/0.8 ML SYRINGE               | 1 or 2 each         | 4 each per 28 days   |
| ADALIMUMAB-ADBM(CF) PEN 40 MG/0.4 ML                   | 1 or 2 each         | 4 each per 28 days   |
| ADALIMUMAB-ADBM(CF) PEN 40 MG/0.8 ML                   | 1 or 2 each         | 4 each per 28 days   |
| ADALIMUMAB-ADBM(CF) PEN CD-UC-HS STAR 40 MG            | 6 each              | 6 (1 kit) per year   |
| ADALIMUMAB-ADBM(CF) PEN CROHN'S-UC-HS START 40 MG/0.4  | 6 each              | 6 (1 kit) per year   |
| ADALIMUMAB-ADBM(CF) PEN PSORIASIS-UVEITIS START 40 MG  | 4 each              | 4 (1 kit) per year   |
| ADALIMUMAB-ADBM(CF) PEN PS-UV START 40 MG              | 4 each              | 4 (1 kit) per year   |
| ADALIMUMAB-FKJP(CF) PEN 40 MG/0.8 ML                   | 1 each              | 4 each per 28 days   |
| ADALIMUMAB-FKJP(CF) 40 MG/0.8 ML SYRG                  | 1 each              | 4 each per 28 days   |
| ADALIMUMAB-RYVK(CF) 40 MG/0.4ML SYRG                   | 1 each              | 4 each per 28 days   |
| ADALIMUMAB-RYVK(CF) AI 40 MG/0.4ML                     | 1 each              | 4 each per 28 days   |
| AMJEVITA(CF) 10 MG/0.2 ML SYRINGE                      | 0.2 mL              | 0.4 mL per 28 days   |
| AMJEVITA(CF) 20 MG/0.4 ML SYRINGE                      | 0.4 mL              | 0.8 mL per 28 days   |
| AMJEVITA(CF) 40 MG/0.8 ML AUTOINJECTOR                 | 0.8 mL              | 3.2 mL per 28 days   |
| AMJEVITA(CF) 40 MG/0.8 ML SYRINGE                      | 0.8 mL              | 3.2 mL per 28 days   |

| <b>TABLE 1 – QUANTITY LIMITS (BIOLOGICS)</b>           |                     | <b>5 Pages Total</b> |
|--|---------------------|----------------------|
| <b>Drug Name</b>                                       | <b>Package Size</b> | <b>Limitation *</b>  |
| BIMZELX 160 MG/ML AUTOINJECTOR                         | 1 or 2 mL           | 2 mL per 28 days     |
| BIMZELX 160 MG/ML SYRINGE                              | 1 or 2 mL           | 2 mL per 28 days     |
| BIMZELX 320 MG/2 ML AUTOINJECT                         | 1 or 2 mL           | 2 mL per 28 days     |
| BIMZELX 320 MG/2 ML SYRINGE                            | 1 or 2 mL           | 2 mL per 28 days     |
| CIMZIA 2X200 MG VIAL KIT                               | 1 each              | 1 each per 28 days   |
| CIMZIA 2X200 MG/ML SYRINGE KIT                         | 1 or 2 each         | 2 each per 28 days   |
| CIMZIA 2X200 MG/ML(X3)START KT                         | 3 each              | 3 (1 kit) per year   |
| COSENTYX (150 MG/ML) 300 MG DOSE-2 SYRINGES            | 1 mL                | 2 mL per 28 days     |
| COSENTYX 150 MG/ML SYRINGE                             | 1 mL                | 1 mL per 28 days     |
| COSENTYX 75 MG/0.5 ML SYRINGE                          | 0.5 mL              | 0.5 mL per 28 days   |
| COSENTYX SENSOREADY 150 MG/ML PEN                      | 1 mL                | 1 mL per 28 days     |
| COSENTYX SENSOREADY 300 MG DOSE/2 PENS (150 MG/PEN)    | 1 mL                | 2 mL per 28 days     |
| COSENTYX UNOREADY 300 MG/2 ML PEN (1 PEN)              | 2 mL                | 2 mL per 28 days     |
| CYLTEZO(CF) 10 MG/0.2 ML SYRINGE                       | 1 each or 2 each    | 2 per 28 days        |
| CYLTEZO(CF) 20 MG/0.4 ML SYRINGE                       | 1 each or 2 each    | 2 per 28 days        |
| CYLTEZO(CF) 40 MG/0.4 ML SYRNG                         | 1 each or 2 each    | 4 per 28 days        |
| CYLTEZO(CF) 40 MG/0.8 ML SYRINGE                       | 1 each or 2 each    | 4 per 28 days        |
| CYLTEZO(CF) PEN 40 MG/0.4 ML                           | 1 or 2 each         | 4 each per 28 days   |
| CYLTEZO(CF) PEN 40 MG/0.8 ML                           | 1 or 2 each         | 4 each per 28 days   |
| CYLTEZO(CF) PEN CD-UC-HS START40 MG/0.8ML              | 6 each              | 6 (1 kit) per year   |
| CYLTEZO(CF) PEN CROHN'S-UC-HS STARTER 40 MG/0.4 ML     | 6 each              | 6 (1 kit) per year   |
| CYLTEZO(CF) PEN PSORIASIS-UVEITIS STARTER 40 MG/0.4 ML | 4 each              | 4 (1 kit) per year   |
| CYLTEZO(CF) PEN PSO-UV START 40 MG/0.8 ML              | 4 each              | 4 (1 kit) per year   |
| ENBREL 25 MG/0.5 ML SYRINGE                            | 0.5 mL or 1 mL      | 4 mL per 28 days     |
| ENBREL 25 MG/0.5 ML VIAL                               | 0.5 mL or 1 mL      | 4 mL per 28 days     |
| ENBREL 50 MG/ML MINI CARTRIDGE                         | 0.5 mL or 1 mL      | 4 mL per 28 days     |
| ENBREL 50 MG/ML SURECLICK                              | 0.5 mL or 1 mL      | 4 mL per 28 days     |
| ENBREL 50 MG/ML SYRINGE                                | 0.5 mL or 1 mL      | 4 mL per 28 days     |
| ENTYVIO 108 MG/0.68 ML PEN                             | 0.68 mL             | 1.36 mL per 28 days  |
| HADLIMA 40 MG/0.8 ML SYRINGE                           | 0.8 mL              | 3.2 mL per 28 days   |
| HADLIMA PUSHTOUCH 40 MG/0.8 ML                         | 0.8 mL              | 3.2 mL per 28 days   |
| HADLIMA(CF) 40 MG/0.4 ML SYRINGE                       | 0.4 mL              | 1.6 mL per 28 days   |
| HADLIMA(CF) PUSHTOUCH 40 MG/0.4 ML                     | 0.4 mL              | 1.6 mL per 28 days   |
| HULIO(CF) 20 MG/0.4 ML SYRINGE                         | 1 each or 2 each    | 2 per 28 days        |
| HULIO(CF) 40 MG/0.8 ML SYRINGE                         | 1 each or 2 each    | 4 per 28 days        |
| HULIO(CF) PEN 40 MG/0.8 ML                             | 1 each or 2 each    | 4 per 28 days        |
| HUMIRA 40 MG/0.8 ML SYRINGE                            | 1 each or 2 each    | 4 per 28 days        |
| HUMIRA PEN 40 MG/0.8 ML                                | 1 each or 2 each    | 4 per 28 days        |
| HUMIRA(CF) 10 MG/0.1 ML SYRINGE                        | 1 each or 2 each    | 2 per 28 days        |
| HUMIRA(CF) 20 MG/0.2 ML SYRINGE                        | 1 each or 2 each    | 2 per 28 days        |
| HUMIRA(CF) 40 MG/0.4 ML SYRINGE                        | 1 each or 2 each    | 4 per 28 days        |

| <b>TABLE 1 – QUANTITY LIMITS (BIOLOGICS)</b>        |                     | <b>5 Pages Total</b>     |
|---|---------------------|--------------------------|
| <b>Drug Name</b>                                    | <b>Package Size</b> | <b>Limitation *</b>      |
| HUMIRA(CF) PEN 40 MG/0.4 ML                         | 1 each or 2 each    | 4 per 28 days            |
| HUMIRA(CF) PEN 80 MG/0.8 ML                         | 1 or 2 each         | 2 each per 28 days       |
| HUMIRA(CF) PEN CRHN-UC-HS 80MG                      | 3 each              | 3 (1 kit) per year       |
| HUMIRA(CF) PEN PS-UV-AHS 80MG-40 MG                 | 3 each              | 3 (1 kit) per year       |
| HYRIMOZ(CF) 10 MG/0.1 ML SYRINGE                    | 0.1 mL              | 0.2 mL per 28 days       |
| HYRIMOZ(CF) 20 MG/0.2 ML SYRINGE                    | 0.2 mL              | 0.4 mL per 28 days       |
| HYRIMOZ(CF) 40 MG/0.4 ML SYRINGE                    | 0.4 mL              | 1.6 mL per 28 days       |
| HYRIMOZ(CF) PED CD START 80 MG/0.8 ML-40 MG/0.4 ML  | 1.2 mL              | 1.2 mL (1 kit) per year  |
| HYRIMOZ(CF) PED CD STARTER 80 MG/0.8 ML SYR         | 0.8 mL              | 0.8 mL (1 kit) per year  |
| HYRIMOZ(CF) PEN 40 MG/0.4 ML                        | 0.4 mL              | 1.6 mL per 28 days       |
| HYRIMOZ(CF) PEN 80 MG/0.8 ML                        | 0.8 mL              | 1.6 mL per 28 days       |
| HYRIMOZ(CF) PEN CD-UC START 80 MG/0.8 ML            | 0.8 mL              | 0.8 mL (1 kit) per year  |
| HYRIMOZ(CF) PEN PS START 80 MG/0.8 ML-40 MG /0.4 ML | 1.6 mL              | 1.6 mL (1 kit) per year  |
| IDACIO(CF) PEN CD-UC START 40                       | 3 each              | 3 (1 kit) per year       |
| IDACIO(CF) PEN PLAQUE PSO START 40 MG/0.8 ML        | 2 each              | 2 (1 kit) per year       |
| ILUMYA 100 MG/ML SYRINGE                            | 1 mL                | 1 mL per 84 days         |
| IMULDOSA 130 MG/26 ML VIAL                          | 1 vial (26 mL)      | 104 mL per 365 days      |
| IMULDOSA 45 MG/0.5 ML SYRINGE                       | 0.5 mL              | 0.5 mL per 84 days       |
| IMULDOSA 90 MG/ML SYRINGE                           | 1 mL                | 1 mL per 84 days         |
| KEVZARA 150 MG/1.14 ML PEN INJ                      | 1.14 mL             | 2.28 mL per 28 days      |
| KEVZARA 150 MG/1.14 ML SYRINGE                      | 1.14 mL             | 2.28 mL per 28 days      |
| KEVZARA 200 MG/1.14 ML PEN INJ                      | 1.14 mL             | 2.28 mL per 28 days      |
| KEVZARA 200 MG/1.14 ML SYRINGE                      | 1.14 mL             | 2.28 mL per 28 days      |
| OLUMIANT 1 MG TABLET                                | 1 each              | 1 each per day           |
| OLUMIANT 2 MG TABLET                                | 1 each              | 1 each per day           |
| OLUMIANT 4 MG TABLET                                | 1 each              | 1 each per day           |
| OMVOH 100 MG/ML PEN                                 | 1 mL                | 2 mL per 28 days         |
| OMVOH 100 MG/ML SYRINGE                             | 1 mL                | 2 mL per 28 days         |
| OMVOH 300 MG DOSE (100 MG/ML-200 MG/2 ML)           | 3 mL                | 3 mL per 28 days         |
| OMVOH PEN 300 MG DOSE (100 MG/ML-200 MG/2 ML)       | 3 mL                | 3 mL per 28 days         |
| ORENCIA 125 MG/ML SYRINGE                           | 0.5 mL or 1 mL      | 4 mL per 28 days         |
| ORENCIA 50 MG/0.4 ML SYRINGE                        | 0.4 mL              | 1.6 mL per 28 days       |
| ORENCIA 87.5 MG/0.7 ML SYRINGE                      | 0.7 mL              | 2.8 mL per 28 days       |
| ORENCIA CLICKJECT 125 MG/ML                         | 0.5 mL or 1 mL      | 4 mL per 28 days         |
| OTEZLA 10-20 MG STARTER 28 DAY                      | 55 each             | 55 each (1 kit) per year |
| OTEZLA 10-20-30 MG START 28 DAY                     | 55 each             | 55 each (1 kit) per year |
| OTEZLA 20 MG TABLET                                 | 1 each              | 2 each per day           |
| OTEZLA 30 MG TABLET                                 | 1 each              | 2 each per day           |
| OTEZLA XR INITIATION PK 28 DAY                      | 41 each             | 41 each (1 kit) per year |
| OTEZLA XR 75 MG TABLET                              | 1 each              | 1 each per day           |
| OTULFI 130 MG/26 ML VIAL                            | 1 vial (26 mL)      | 104 mL per 365 days      |

| <b>TABLE 1 – QUANTITY LIMITS (BIOLOGICS)</b> |                     | <b>5 Pages Total</b> |
|--|---------------------|----------------------|
| <b>Drug Name</b>                             | <b>Package Size</b> | <b>Limitation *</b>  |
| OTULFI 45 MG/0.5 ML SYRINGE                  | 0.5 mL              | 0.5 mL per 84 days   |
| OTULFI 45 MG/0.5 ML VIAL                     | 0.5 mL              | 0.5 mL per 84 days   |
| OTULFI 90 MG/ML SYRINGE                      | 1 mL                | 1 mL per 84 days     |
| PYZCHIVA 130 MG/26 ML VIAL                   | 1 vial (26 mL)      | 104 mL per 365 days  |
| PYZCHIVA 45 MG/0.5 ML SYRINGE                | 0.5 mL              | 0.5 mL per 84 days   |
| PYZCHIVA 45 MG/0.5 ML VIAL                   | 0.5 mL              | 0.5 mL per 84 days   |
| PYZCHIVA 90 MG/ML SYRINGE                    | 1 mL                | 1 mL per 84 days     |
| RINVOQ ER 15 MG TABLET                       | 1 each              | 1 each per day       |
| RINVOQ ER 30 MG TABLET                       | 1 each              | 1 each per day       |
| RINVOQ ER 45 MG TABLET                       | 1 each              | 1 each per day       |
| RINVOQ LQ 1 MG/ML SOLUTION                   | 1 mL                | 12 mL per day        |
| SELARSDI 130 MG/26 ML VIAL                   | 1 vial (26 mL)      | 104 mL per 365 days  |
| SELARSDI 45 MG/0.5 ML SYRINGE                | 0.5 mL              | 0.5 mL per 84 days   |
| SELARSDI 45 MG/0.5 ML VIAL                   | 0.5 mL              | 0.5 mL per 84 days   |
| SELARSDI 90 MG/ML SYRINGE                    | 1 mL                | 1 mL per 84 days     |
| SIMLANDI(CF) 20 MG/0.2 ML SYRINGE            | 1 each or 2 each    | 2 per 28 days        |
| SIMLANDI(CF) 40 MG/0.4 ML AUTOINJECTOR       | 1 each or 2 each    | 4 per 28 days        |
| SIMLANDI(CF) 40 MG/0.4 ML SYRINGE            | 1 each or 2 each    | 4 per 28 days        |
| SIMLANDI(CF) 80 MG/0.8 ML AUTOINJECTOR       | 1 each or 2 each    | 2 per 28 days        |
| SIMLANDI(CF) 80 MG/0.8 ML SYRINGE            | 1 each or 2 each    | 2 per 28 days        |
| SIMPONI 100 MG/ML PEN INJECTOR               | 1 mL                | 1 mL per 28 days     |
| SIMPONI 100 MG/ML SYRINGE                    | 1 mL                | 1 mL per 28 days     |
| SIMPONI 50 MG/0.5 ML PEN INJEC               | 0.5 mL              | 0.5 mL per 28 days   |
| SIMPONI 50 MG/0.5 ML SYRINGE                 | 0.5 mL              | 0.5 mL per 28 days   |
| SKYRIZI 150 MG/ML PEN                        | 1 mL                | 1 mL per 84 days     |
| SKYRIZI 150 MG/ML SYRINGE                    | 1 mL                | 1 mL per 84 days     |
| SKYRIZI 180 MG/1.2 ML ON-BODY                | 1.2 mL              | 1.2 mL per 56 days   |
| SKYRIZI 360 MG/2.4 ML ON-BODY                | 2.4 mL              | 2.4 mL per 56 days   |
| SOTYKTU 6 MG TABLET                          | 1 each              | 1 each per day       |
| STELARA 130 MG/26 ML VIAL                    | 1 vial (26 mL)      | 104 mL per 365 days  |
| STARJEMZA 45 MG/0.5 ML SYRINGE               | 0.5 mL              | 0.5 mL per 84 days   |
| STARJEMZA 45 MG/0.5 ML VIAL                  | 0.5 mL              | 0.5 mL per 84 days   |
| STARJEMZA 90 MG/ML SYRINGE                   | 1 mL                | 1 mL per 84 days     |
| STARJEMZA 130 MG/26 ML VIAL                  | 1 vial (26 mL)      | 104 mL per 365 days  |
| STELARA 45 MG/0.5 ML SYRINGE                 | 0.5 mL              | 0.5 mL per 84 days   |
| STELARA 45 MG/0.5 ML VIAL                    | 0.5 mL              | 0.5 mL per 84 days   |
| STELARA 90 MG/ML SYRINGE                     | 1 mL                | 1 mL per 84 days     |
| STEQEYMA 130 MG/26 ML VIAL                   | 1 vial (26 mL)      | 104 mL per 365 days  |
| STEQEYMA 45 MG/0.5 ML SYRINGE                | 0.5 mL              | 0.5 mL per 84 days   |
| STEQEYMA 90 MG/ML SYRINGE                    | 1 mL                | 1 mL per 84 days     |
| TALTZ 20 MG/0.25 ML SYRINGE                  | 0.25 mL             | 0.25 mL per 28 days  |

| <b>TABLE 1 – QUANTITY LIMITS (BIOLOGICS)</b>   |                     | <b>5 Pages Total</b> |
|--|---------------------|----------------------|
| <b>Drug Name</b>                               | <b>Package Size</b> | <b>Limitation *</b>  |
| TALTZ 40 MG/0.5 ML SYRINGE                     | 0.5 mL              | 0.5 mL per 28 days   |
| TALTZ 80 MG/ML AUTOINJECTOR                    | 1 mL                | 1 per 28 days        |
| TALTZ 80 MG/ML AUTOINJECTOR (2-PACK)           | 1 mL                | 2 (2 kits) per year  |
| TALTZ 80 MG/ML AUTOINJECTOR (3-PACK)           | 1 mL                | 1 (1 kit) per year   |
| TALTZ 80 MG/ML SYRINGE                         | 1 mL                | 1 mL per 28 days     |
| TREMFYA 100 MG/ML INJECTOR                     | 1 mL                | 1 mL per 56 days     |
| TREMFYA 100 MG/ML PEN                          | 1 mL                | 1 mL per 56 days     |
| TREMFYA 100 MG/ML SYRINGE                      | 1 mL                | 1 mL per 56 days     |
| TREMFYA 200 MG/2 ML PEN                        | 1 or 2 mL           | 2 mL per 28 days     |
| TREMFYA 200 MG/2 ML SYRINGE                    | 1 or 2 mL           | 2 mL per 28 days     |
| TYENNE 162 MG/0.9 ML AUTOINJCT                 | 0.9 mL              | 3.6 mL per 28 days   |
| TYENNE 162 MG/0.9 ML SYRINGE                   | 0.9 mL              | 3.6 mL per 28 days   |
| USTEKINUMAB 130 MG/26 ML VIAL                  | 1 vial (26 mL)      | 104 mL per 365 days  |
| USTEKINUMAB 45 MG/0.5 ML SYRINGE               | 0.5 mL              | 0.5 mL per 84 days   |
| USTEKINUMAB 45 MG/0.5 ML VIAL                  | 0.5 mL              | 0.5 mL per 84 days   |
| USTEKINUMAB 90 MG/ML SYRINGE                   | 1 mL                | 1 mL per 84 days     |
| USTEKINUMAB-AAUZ 45 MG SYRINGE                 | 0.5 mL              | 0.5 mL per 84 days   |
| USTEKINUMAB-AAUZ 90 MG/ML SYR                  | 1 mL                | 1 mL per 84 days     |
| USTEKINUMAB-AEKN- 45MG/0.5ML SY                | 0.5 mL              | 0.5 mL per 84 days   |
| USTEKINUMAB-AEKN 90 MG/ML SYRINGE              | 1 mL                | 1 mL per 84 days     |
| USTEKINUMAB-TTWE 130MG/26ML VL                 | 1 vial (26 mL)      | 104 mL per 365 days  |
| USTEKINUMAB-TTWE 45MG/0.5ML SY                 | 0.5 mL              | 0.5 mL per 84 days   |
| USTEKINUMAB-TTWE 90 MG/ML SYR                  | 1 mL                | 1 mL per 84 days     |
| VELSIPITY 2 MG TABLET                          | 1 each              | 1 each per day       |
| XELJANZ 1 MG/ML SOLUTION                       | 1 mL                | 10 mL per day        |
| XELJANZ 10 MG TABLET                           | 1 each              | 2 each per day       |
| XELJANZ 5 MG TABLET                            | 1 each              | 2 each per day       |
| XELJANZ XR 11 MG TABLET                        | 1 each              | 1 each per day       |
| XELJANZ XR 22 MG TABLET                        | 1 each              | 1 each per day       |
| YESINTEK 130 MG/26 ML VIAL                     | 1 vial (26 mL)      | 104 mL per 365 days  |
| YESINTEK 45 MG/0.5 ML SYRINGE                  | 0.5 mL              | 0.5 mL per 84 days   |
| YESINTEK 45 MG/0.5 ML VIAL                     | 0.5 mL              | 0.5 mL per 84 days   |
| YESINTEK 90 MG/ML SYRINGE                      | 1 mL                | 1 mL per 84 days     |
| YUFLYMA(CF) 20 MG/0.2 ML SYRINGE (2 PACK)      | 1 each              | 1 each per 28 days   |
| YUFLYMA(CF) 40 MG/0.4 ML AUTOINJECTOR          | 1 or 2 each         | 4 each per 28 days   |
| YUFLYMA(CF) 40 MG/0.4 ML AUTOINJECTOR (2 PACK) | 1 each              | 2 each per 28 days   |
| YUFLYMA(CF) 40 MG/0.4 ML SYRINGE (2 PACK)      | 1 each              | 2 each per 28 days   |
| YUFLYMA(CF) 80 MG/0.8 ML AUTOINJECTOR          | 1 or 2 each         | 2 each per 28 days   |
| YUFLYMA(CF) AUTOINJ CD-UC-HS START 80 MG       | 3 each              | 3 (1 kit) per year   |
| YUSIMRY(CF) 40 MG/0.8 ML PEN                   | 0.8 mL              | 3.2 mL per 28 days   |
| ZYMFENTRA 120 MG/ML PEN KIT                    | 1 or 2 each         | 2 each per 28 days   |

| TABLE 1 – QUANTITY LIMITS ( <a href="#">BIOLOGICS</a> ) |              | 5 Pages Total      |
|---|--------------|--------------------|
| Drug Name   | Package Size | Limitation *       |
| ZYMFENTRA 120 MG/ML PEN KIT (2 PACK)                    | 1 each       | 1 each per 28 days |

***Disclaimer: Some agents listed may still be under formulary review and are included with quantity limits for future reference purposes only. Quantity Limits are subject to change, and updates may occur between postings of this document.***

***\* For loading doses of the biologic products listed in the 'Quantity Limits (Biologics)' table above, a date-of-service override will be granted for quantity limit exceptions.***

## INCRETIN MIMETICS AND COMBINATIONS

### Drug Class:

- Incretin Mimetics
- Incretin Mimetics - Combinations

### ❖ **INCRETIN MIMETICS**

**Preferred Agents:** *Clinical Prior Authorization below*

Byetta®  
Ozempic®  
Trulicity®  
Victoza®

### **Clinical Preferred Agent PA Criteria:**

- Patient has a diagnosis of type 2 diabetes; **AND**
- Discontinuation of other GLP-1 agonists; **AND**
- Discontinuation of DPP4 Inhibitors

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Bydureon Bcise®  
exenatide  
liraglutide  
Mounjaro®  
Rybelsus®

### ❖ **INCRETIN MIMETICS – COMBINATIONS**

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Soliqua®  
Xultophy®

### **Non-Preferred Agent PA Criteria:**

- Diagnosis of type 2 diabetes; **AND**
- Discontinuation of other GLP-1 agonists; **AND**
- Discontinuation of DPP4 Inhibitors; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with one preferred medication within same subgroup
- **See additional medication-specific criteria below:**

**SOLIQUA® (INSULIN GLARGINE/LIXISENATIDE)**

- One-month trial and failure with one of the preferred medications in each subgroup of the components (basal insulin and GLP-1 agonist)

**XULTOPHY® (INSULIN DEGLUDEC/LIRAGLUTIDE)**

- One-month trial and failure with one of the preferred medications in each subgroup of the components (basal insulin and GLP-1 agonist)

**QUANTITY LIMITS**

|  |  |
|--|--|
| Bydureon Bcise 2mg Auto Inject                       | 3.4 mls per 28 days (4 doses per 28 days)                                |
| Byetta Dose Pen Injector/exenatide dose pen injector | 10mcg - 2.4 mls per 30 days<br>5mcg - 1.2 mls per 30 days                |
| Mounjaro Pens  | 2 mls per 28 days  |
| Ozempic Pens   | 3 mls per 28 days  |
| Rybelsus Tablets                                     | 1 per day  |
| Soliqua 100 unit-33mcg/ml Pen                        | 15 mls per 25 days   |
| Trulicity Pens                                       | 2 mls per 28 days  |
| Victoza Pens (brand and generic)                     | 2-Pak 18mg/3ml - 6 mls per 30 days<br>3-Pak 18mg/3ml - 9 mls per 30 days |
| Xultophy 100 unit-3.6mg/ml Pen                       | 15 mls per 30 days   |

- Duration of Approval:** Up to 1 year

# INGREZZA/ VALBENAZINE

**Drug Class** Movement Disorder Therapy - Tardive Dyskinesia, Huntington's Disease

**FDA-approved uses:** Tardive Dyskinesia, Chorea associated with Huntington's

**Available dosage forms:** Capsules: 40mg, 60mg, 80mg, Initiation Pack, and  
Sprinkles: 40mg, 60mg, 80mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Diagnosis of chorea associated with Huntington's disease; **OR**
  - Diagnosis of tardive dyskinesia secondary to use of a dopamine antagonist (i.e., antipsychotic, metoclopramide, prochlorperazine, droperidol, promethazine, etc.)
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by or in consultation with a neurologist or psychiatrist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - For tardive dyskinesia attestation that a baseline AIMS test has been completed
- Age:** Patient is 18 years of age or older

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Attestation of patient's improvement in symptoms associated with their condition; **AND**
  - For tardive dyskinesia attestation that a follow-up AIMS test has been completed and there has been a positive response to therapy

**QUANTITY LIMITS**

|   |                          |
|---|--------------------------|
| Ingrezza Capsules (40mg, 60mg, 80mg)          | 30 capsules per 30 days  |
| Ingrezza Initiation pack                      | 28 capsules per 365 days |
| Ingrezza Sprinkle Capsules (40mg, 60mg, 80mg) | 30 capsules per 30 days  |

## INHALED GLUCOCORTICIDS

**Drug Class:** Inhaled Glucocorticoids

**Preferred Agents:** *No Prior Authorization required*

Alvesco® (MDI)  
Arnuity Ellipta® (DPI)  
Asmanex® Twisthaler (DPI)  
Asmanex HFA® (DPI)  
budesonide 0.25 and 0.5mg nebulizer solution  
budesonide 1mg nebulizer solution (generic for Pulmicort Respules)  
fluticasone Prop HFA (Generic Flovent HFA)  
Pulmicort Flexihaler® (DPI)  
QVAR Redihaler® (MDI)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Armonair Digihaler  
beclomethasone dipropionate HFA (generic for QVAR)  
fluticasone prop diskus (Generic Flovent Diskus)  
fluticasone ellipta (Generic Arnuity Ellipta)  
Pulmicort® 1mg Respules nebulizer solution  
Pulmicort® 0.25mg and 0.5mg Respules

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a two-week trial with one preferred medication; **OR**
- For children less than 13 years of age or a patient with a significant disability: inability to use the inhaler on preferred medications, or non-compliance because of taste, dry mouth
- **See additional medication-specific criteria below:**

**ASMANEX® Twisthaler 110mcg (MOMETASONE) ONLY – Age Limit**

- Requests submitted to exceed the age limit of 11 years may be approved if a lower dose is needed and the dose requested does not exceed 1 inhaler per 30 days

**QUANTITY LIMITS**

|   |                           |
|---|---------------------------|
| Asmanex (mometasone) HFA                | 3 inhaler per 90 days     |
| Asmanex (mometasone) Twisthaler         | 1 inhaler per fill        |
| Pulmicort 90mcg Flexhaler (budesonide)  | 3 inhaler per 90 days     |
| Pulmicort 180mcg Flexhaler (budesonide) | 6 inhalers per 90 days    |
| Pulmicort Respules (budesonide)         | 2 respules (4mls) per day |

**MAXIMUM AGE LIMITS**

|  |          |
|--|----------|
| Arnuity Ellipta (fluticasone) 50 mcg         | 11 years |
| Asmanex (mometasone) HFA 50 mcg              | 12 years |
| Asmanex (mometasone) Twisthaler 110 mcg      | 11 years |
| Pulmicort 0.25 mg/2 ml Respules (budesonide) | 8 years  |
| Pulmicort 0.5 mg/2 ml Respules (budesonide)  | 8 years  |
| Pulmicort 1 mg/2 ml Respules (budesonide)    | 8 years  |

**Duration of Approval:** 1 year

## INSULIN SUPPRESSANTS

**Drug Class:** Insulin Suppressants

**Preferred Agents:** *No Prior Authorization required*

Proglycem

**Non-Preferred Agents:** *Prior Authorization Criteria below*

diazoxide (generic for Proglycem)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- History of trial and failure with one preferred medication

**Duration of Approval:** 1 year

## INSULINS

### **Drug Class:**

- Insulins, Mixes
- Insulins, Basal
- Insulins, Rapid Acting
- Insulins, Traditional

### ❖ **INSULINS, MIXES**

**Preferred Agents:** *No Prior Authorization required*

Humalog® 50/50 Kwikpens  
Humulin® 70/30 Kwikpens, vials  
insulin aspart 70/30 pens, vials  
insulin lispro mix 75-25 Kwikpen  
Humalog® 75/25 vials

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Novolin® 70/30 pens, vials  
Novolog® 70/30 pens, vials  
Humalog® 75/25 pens

### ❖ **INSULINS, BASAL**

**Preferred Agents:** *No Prior Authorization required*

Lantus® pens, vials  
Levemir® pens, vials

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Basaglar® Kwikpens, Tempo Pens  
insulin degludec pens, vials  
insulin glargine-YFGN pens , vials (biosimilar for Semglee®)  
insulin glargine solostar/max solostar U300 pens (generic for Toujeo)  
Rezvoglar®  
Semglee® (YFGN) pens, vials  
Toujeo Solostar/Max Solostar® pens  
Tresiba Flextouch® pens, vials

## ❖ **INSULINS, RAPID ACTING**

**Preferred Agents:** *No Prior Authorization required*

insulin aspart pens, vials  
Humalog® U-100 cartridges, Kwikpens, Tempo Pens, vials  
insulin lispro U-100 Kwikpens, vials (gen for Humalog)  
insulin aspart cartridges

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Admelog® vials; Admelog Solostar® pens  
Afrezza® inhalation cartridges  
Apidra® pens, vials  
Fiasp® pens, vials, Pumpcart  
Humalog® U-200 Kwikpens  
Kirsty® pens, vials  
Lyumjev®, Kwikpens, Tempo Pens  
Merilog® (insulin aspart-szjj)  
Merilog Solostar® (insulin aspart-szjj)  
Novolog® pens, vials  
Novolog® cartridges

## ❖ **INSULINS, TRADITIONAL**

**Preferred Agents:** *No Prior Authorization required*

Humulin® R U-500 pens, vials  
Humulin® N Kwikpens  
Humulin® N vials  
Humulin® R vials

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Novolin® N vials  
Novolin® R vials

### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one preferred medication within same subgroup
- **See additional medication-specific criteria below:**

**KIRSTY® (INSULIN ASPART-XJHZ)**

- Quantity limit = 90 per fill

**LYUMJEV™ (INSULIN LISPRO-AABC)**

- Quantity limit = 90 per fill

**MERILOG® (INSULIN ASPART-SZJJ)**

- Quantity limit = 90 ml per fill

**MERILOG SOLOSTAR® (INSULIN ASPART-SZJJ)**

- Quantity limit = 90 ml per fill

**REZVOGLAR® (INSULIN GLARGINE-AGLR)**

- Quantity limit = 90 per fill

**Duration of Approval:** 1 year

## ISOTRETINOIN / CLARAVIS®

## ISOTRETINOIN / AMNESTEEM®

## ISOTRETINOIN / ZENATANE™

**Drug Class:** Acne Therapy Systemic - Retinoids & Derivatives

**Available dosage forms:** Claravis Capsule 10 mg, 20 mg, 30 mg, and 40 mg; Amnesteem Capsule 10mg, 20mg and 40mg; Zenatane Capsule 10mg, 20mg, 30mg and 40mg

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Severe acne or severe (multiple locations) nodular acne  
Documentation that the patient's has severe nodular acne as demonstrated by one or more of the following:
  - Visually prominent acne consisting of many comedones, inflamed papules, or pustules
  - Presence of large, inflamed papules or nodules (lesions >5 mm in diameter)
  - Associated scarring
- Duration of Approval**
  - **Initial Authorization:** 5 months
  - **Second Authorization:** Reviewed for coverage after a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne; 5 months
- Prescriber Specialty:** Dermatologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Must be prescribed by a dermatologist **AND**
  - Attestation that patient meets the requirements of the iPledge Program **AND**
    - Current chart notes detailing the diagnosis **AND**
    - One of the following diagnoses:
      - Diagnosis of severe nodular acne **OR**
      - Diagnosis of moderate to severe acne without nodules **AND**
        - Failed/intolerant to at least a 3-month consistent trial of 1 oral antibiotic used for treatment of acne **AND**
        - Failed/intolerant to at least a 3-month consistent trial of 1 topical retinoid **AND**
        - Failed/intolerant to at least a 3-month consistent trial of benzoyl peroxide
- Age:** 12 years and older
- Route of Administration:** Oral

### **Criteria for second authorization:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Medical records from first round of isotretinoin treatment demonstrate compliance with monthly provider visits, medication adherence, and improvement or stability on drug
  - Continues to meet the requirements of the iPledge program

## JYNARQUE/ TOLVAPTAN

**Drug Class** : Vasopressin V<sub>2</sub>-receptor antagonist

**FDA-approved uses**: Indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

**Available dosage forms**: 15mg, 30mg, 15-15mg, 30-15mg, 45-15mg, 60-30mg, 90-30mg

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses**: Autosomal dominant polycystic kidney disease (ADPKD)
- Duration of approval**:
  - **Initial authorization**: 1 year
  - **Continuation of Therapy**: 1 year
- Prescriber Specialty**: Nephrologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed via imaging (supporting documentation must be submitted)
  - Attestation of baseline ALT, AST, and bilirubin tests within normal limits
  - Have an estimated glomerular filtration rate (eGFR) of  $\geq 25\text{mL}/\text{min}/1.73\text{m}^2$
  - Have disease that is rapidly progressing or likely to rapidly progress as evidenced by:
    - Total kidney volume (TKV) of at least 750mL, **OR**
    - Rapid loss of eGFR of at least  $2.5\text{mL}/\text{min}/1.73\text{m}^2$  per year;
- Age**: 18 years of age and older
- Quantity Limit**: 2 tablets/day

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Attestation of baseline ALT, AST, and bilirubin tests continue to be within normal limits

### **Other special considerations:**

- Prescribers must be certified by enrolling in the REMS program.
- Pharmacies must be certified by enrolling in the REMS program and must only dispense to patients who are authorized to receive Jynarque.

## KERENDIA / FINERENONE

**Drug Class:** Mineralocorticoid (Aldosterone) Receptor Antagonists

**FDA-approved uses:**

- chronic kidney disease (CKD) with type 2 diabetes
- Symptomatic chronic heart failure

**Available dosage forms:** 10mg, 20mg, 40mg tablets

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** diagnosis of chronic kidney disease (CKD) with type 2 diabetes
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **chronic kidney disease (CKD) with type 2 diabetes**
    - Member is currently receiving a maximally tolerated dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) OR has a contraindication to ACE inhibitor or ARB therapy AND
    - Member is not taking any strong CYP3A4 inhibitors AND
    - Member at baseline member meets all of the following:
      - Estimated glomerular filtration rate (eGFR)  $\geq 25\text{ml}/\text{min}/1.73\text{m}^2$  AND
      - Urine albumin-to-creatinine ratio  $>30\text{mg}/\text{g}$  AND
      - Serum potassium level  $<5.0\text{mEq}/\text{L}$
  - **Symptomatic chronic heart failure**
    - Have a diagnosis of chronic heart failure (NYHA Class II-IV); **AND**
    - Patient is at least 18 years of age; **AND**
    - Must be prescribed by, or in consultation with (notes must be submitted), a cardiologist; **AND**
    - Patient has been using at least 2 of the following HF medications at goal doses for HF treatment or maximally tolerated dosing:
      - ACE inhibitor, ARB, or Entresto
      - Beta blocker (e.g., Bisoprolol, carvedilol, or sustained release metoprolol)
      - Spironolactone
      - Oral diuretic (e.g., furosemide); **AND**
    - Documented LVEF of  $\geq 40\%$  assessed within the previous 12 months; **AND**
    - At baseline, members meet all the following:
      - Estimated glomerular filtration rate (eGFR)  $\geq 25\text{ml}/\text{min}/1.73\text{m}^2$ ; AND
      - Serum potassium level  $<5.0\text{mEq}/\text{L}$
- Quantity:** 1 per day
- Age:** minimum 18 years

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Member has eGFR  $\geq 25$ ml/min/1.73m<sup>2</sup> **AND**
  - Member serum potassium level  $< 5.0$ mEq/L

**Contraindications/Exclusions/Discontinuation:** concomitant strong CYP3A4 inhibitors, adrenal insufficiency

## KRINTAFEL® / TAFENOQUINE

**Drug Class:** Antimalarials

**FDA-approved uses:**

- Indicated for the radical cure (prevention of relapse) of *Plasmodium vivax* malaria in patients aged 16 years and older who are receiving appropriate antimalarial therapy for acute *P. vivax* infection. It is not indicated for the treatment of acute *P. vivax* malaria

**Available dosage forms:** 150 mg tablet

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Prevention of *Plasmodium vivax*
- Duration of approval:**
  - **Initial authorization:**
    - *Plasmodium vivax* – one-time single dose
  - **Continuation of Therapy:**
    - A repeat dose should be given if vomiting occurs within 1 hour after dosing. Re-dosing should not be attempted more than once.
- Prescriber Specialty:** infectious disease
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Medical record
  - Must be tested negative for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to prescribing
  - Negative pregnancy test result in all women of reproductive potential
  - Breastfeeding an infant found to be G6PD deficient or unknown status is contraindicated
- Quantity:** Two (2), 150 mg tablets per 365 days
- Age:** 16 years of age and older
- Gender:** males and non-pregnant and non-lactating females
- Route of Administration:** Oral
- Place of Service:** Outpatient

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Updated medical record

**Contraindications/Exclusions/Discontinuation:**

- Glucose-6-phosphate dehydrogenase (G6PD) deficiency or unknown G6PD status
- May cause hemolytic anemia for patients when administered to pregnant woman with a G6PD-deficient fetus. A G6PD-deficient infant may be at risk for hemolytic anemia from exposure through breast milk. Check infant's G6PD status before breastfeeding begins
- Patients with known hypersensitivity to tafenoquine, other 8-aminoquinolines, or any component of Krintafel

**Other special considerations:**

- Refer to the CDC website for recommendations for treatment and prevention of *Plasmodium vivax* malaria.

# MEFLOQUINE

**Drug Class:** Antimalarial

**FDA-approved uses:**

- Treatment of Acute Malaria Infections:** Mefloquine is indicated for the treatment of mild to moderate acute malaria caused by mefloquine-susceptible strains of *P. falciparum* (both chloroquine-susceptible and resistant strains) or by *P. vivax*.
- Prevention of Malaria:** Mefloquine is indicated for the prophylaxis of *P. falciparum* and *P. vivax* malaria infections, including prophylaxis of chloroquine-resistant strains of *P. falciparum*.

**Available dosage forms:** 250mg Tablets

**Coverage Criteria/Limitations for initial authorization** [30 days for acute treatment; 3 months for prophylaxis]:

- Diagnoses:** treatment or prevention of malaria
- Duration of Approval:**
  - **Initial Authorization:**
    - Acute Treatment: 30 days
    - Prophylaxis: 3 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Country/region where the patient will be traveling
  - For Acute Treatment:
    - cultures and sensitivities to support malaria diagnosis
  - For Malaria Prophylaxis:
    - date and duration of travel
    - Use of doxycycline
- Quantity:** 5 tablets per 30 days
- Gender:** male or female
- Route of Administration:** oral
- Place of Service:** outpatient

**Contraindications/Exclusions/Discontinuation:**

- Mefloquine should not be prescribed for prophylaxis in patients with active depression, a recent history of depression, generalized anxiety disorder, psychosis, schizophrenia or other major psychiatric disorders, or with a history of convulsions.
- Mefloquine is contraindicated with the use of ketoconazole.
- Mefloquine should be used with caution with potent CYP3A4 inhibitors and medications that prolong the QTc interval.
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## LEUKOTRIENE INHIBITORS

**Drug Class:** Leukotriene Inhibitors

**Preferred Agents:** *See Age Criteria for chew tablets below*

montelukast tablets, 4mg chew tabs, 5mg chew tabs

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Accolate®  
montelukast granules  
Singulair® tablets, 4mg chew tabs, 5mg chew tabs, granules  
zafirlukast  
Zileuton ER®  
Zyflo®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure with one month with one preferred medication

**MONTELUKAST (SINGULAIR®)**

- clinical rationale why the (swallow) tablet dosage form inappropriate for the following age limits:
  - 4mg chew tabs – prior authorization (PA) required for patients > 5
  - 5mg chew tabs – PA required for patients > 14
  - Granules – PA required for patients > 5; Requests for granules for patients <5 may bypass PDL criteria if the patient is unable to chew or swallow a tablet.

**Duration of Approval:** 1 year

## LIDOCAINE 5% PATCH

**Drug Class:** Dermatological - Topical Local Anesthetic Amides

**FDA-approved uses:** Post-herpetic neuralgia (PHN)

**Available dosage forms:** Lidocaine 5% patch

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** (any of the following)
  - Post-herpetic neuralgia (PHN)
  - Diabetic neuropathic pain
  - Peripheral polyneuropathy not due to post-herpetic neuralgia, diabetes, or cancer with history of substance use disorder (SUD)
  - SUD related concerns
- Duration of Approval:**
  - **Initial Authorization:**
    - PHN: Up to 90 days
    - Neuropathic pain: initially 2 months
    - Pain with SUD related concerns: Up to 6 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **For diabetic neuropathic pain only:** Trial of at least 2 of the following or contraindication to all of the following:
    - Gabapentin
    - tricyclic antidepressant
    - nerve block
    - trigger point injection
    - SNRIs
    - TENS unit
- Quantity:** Max 3 patches per day (may be cut to cover areas of most severe pain)

**Criteria for continuation of therapy:**

- Requires positive response to the use of the patch
- Duration of approval: Up to 12 months

**Contraindications/Exclusions/Discontinuation:**

- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## LIPOTROPICS: FIBRIC ACID DERIVATIVES

**Drug Class:** Lipotropics: Fibric Acid Derivatives

**Preferred Agents:** *No Prior Authorization required*

fenofibrate, nanocrystallized (generic for Tricor®)  
fenofibric acid capsules (generic for Lofibra® caps)  
fenofibrate tablets (generic for Lofibra tablets)  
gemfibrozil

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Antara®  
fenofibrate, micronized capsules (generic for Antara)  
fenofibrate, nanocrystallized (generic for Triglide®)  
fenofibric acid (generic for Fibracor)  
fenofibric acid (generic for Trilipix®)  
Fibracor®  
Lopid®  
Lipofen®  
Tricor®  
Trilipix®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## LIPOTROPICS: NIACIN DERIVATIVES

**Drug Class:** Lipotropics: Niacin Derivatives

**Preferred Agents:** *No Prior Authorization required*

niacin tablets (OTC)  
niacin ER tablets (OTC)  
niacin ER capsules (OTC)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

niacin ER (generic for Niaspan)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## LIPOTROPICS: NON-STATINS - BILE ACID SEQUESTRANTS

**Drug Class:** Lipotropics: Non-Statins - Bile Acid Sequestrants

**Preferred Agents:** *No Prior Authorization required*

cholestyramine/ cholestyramine light  
colestipol tablets  
Prevalite powder, packets

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Colestid® tablet  
colestipol granules  
colesevelam tablet, packet  
Questran®/ Questran Light®  
Welchol® powder and tablets

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Patient is clinically stable, and switching would cause a deterioration in condition
- Therapeutic failure with one-month trial of one preferred medication

**Duration of Approval:** 1 year

## LIPOTROPICS: OTHERS

**Drug Class:** Lipotropics: Others

**Preferred Agents:** *No Prior Authorization required*

ezetimibe

**Non-Preferred Agents:** *Prior Authorization Criteria below*

icosapent ethyl  
Nexletol®  
Nexlizet®  
omega-3 acid ethyl esters capsule  
Zetia®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**OMEGA-3 ACID ETHYL ESTERS – PDL CRITERIA DO NOT APPLY**

- Adjunct to diet to reduce severe triglyceride (TG) levels (hypertriglyceridemia) in adult patients.
- Triglyceride levels  $\geq 500$  mg/Dl

**NEXLETOL® (BEMPEDOIC ACID) – PDL CRITERIA DO NOT APPLY**

- Patient is  $\geq 18$  years of age; **AND**
- Established atherosclerotic cardiovascular disease (ASCVD); **OR**
- Heterozygous familial hypercholesterolemia; **AND**
- Failure to achieve target LDL-C on maximally tolerated doses of statins; **AND**
- Therapy will used in conjunction with maximally tolerated doses of a statin

**NEXLIZET® (BEMPEDOIC ACID/EZETIMIBE) – PDL CRITERIA DO NOT APPLY**

- Patient is  $\geq 18$  years of age; **AND**
- Established atherosclerotic cardiovascular disease (ASCVD); **OR**
- Heterozygous familial hypercholesterolemia; **AND**
- Failure to achieve target LDL-C on maximally tolerated doses of statins; **AND**
- Therapy will used in conjunction with maximally tolerated doses of a statin

**ICOSAPENT ETHYL – PDL CRITERIA DO NOT APPLY**

- Adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia ; **OR**
- Adjunct to maximally tolerated statin therapy in adult patients with elevated triglyceride (TG) levels ( $\geq 150$  mg/dL) and one of the following; **AND**
  - Established cardiovascular disease; **OR**
  - Diabetes mellitus and 2 or more additional risk factors for cardiovascular disease (i.e., men  $>55$  years and women  $>65$  years, cigarette smoker or stopped smoking within the past 3 months, hypertension (pretreatment blood pressure  $>140$ mmHg systolic or  $>90$ mmHg diastolic))

☐ **Duration of Approval:** 1 year

## LIPOTROPICS: PCSK9 INHIBITORS

**Drug Class:** Lipotropics: proprotein convertase subtilisin kexin type 9 (PCSK9) Inhibitors

**FDA Approved Indications:**

- To reduce the risk of major adverse cardiovascular (CV) events (CV death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events
- As an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in the following:
  - Adults with hypercholesterolemia
  - Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH)
  - Adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH)

**Preferred Agents:** *Clinical Prior Authorization criteria below*

Praluent®

Repatha®

**REPATHA® (EVOLOCUMAB) AND PRALUENT® (ALIROCUMAB)**

**Initial Request**

- Diagnosis of one of the following:
  - atherosclerotic cardiovascular disease (ASCVD); **OR**
  - heterozygous familial hypercholesterolemia (HeFH); **OR**
  - homozygous familial hypercholesterolemia (HoFH); **OR**
  - hypercholesterolemia; **AND**
- A treatment failure despite high intensity or maximally tolerated dose of statin (atorvastatin or rosuvastatin) for at least 8 weeks.
- If intolerant to statins, this must be supported by submitted chart notes/labs; **AND**
- Patient has failed to reach target LDL-C levels (document lab values):
  - ASCVD: LDL-C is < 70 mg/dL with option to target <55 mg/dL.
  - HeFH or HoFH: No LDL-C value required

**Length of Authorization: Initial** – 12 months; **Renewal** – 12 months

**Renewal Criteria:** Lipid panel showing a further reduction in LDL-C compared to the labs prior to initiating medication

**Quantity Limits:**

| <b>Drug Name</b>                        | <b>Package Size</b>      | <b>Limitation</b>           |
|---|--------------------------|-----------------------------|
| <b>PRALUENT®</b>                        | 75 mg/ml pen             | 2 pens/syringes per 28 days |
| <b>PRALUENT®</b>                        | 150 mg/ml pen            | 2 pens/syringes per 28 days |
| <b>REPATHA®</b>                         | 140 mg/mL pen/syringe    | 2 pens/syringes per 28 days |
| <b>REPATHA®</b> (for diagnosis of HoFH) | 420 mg/3.5 mL Pushtonex® | 7mls per 28 days            |

**Duration of Approval:** 1 year

## LIPOTROPICS: STATINS

**Drug Class:** Lipotropics: Statins

**Preferred Agents:** *No Prior Authorization required*

atorvastatin  
ezetimibe/simvastatin  
lovastatin  
pravastatin  
rosuvastatin  
simvastatin

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                              |              |
|------------------------------|--------------|
| amlodipine / atorvastatin    | Lescol XL®   |
| Altoprev®                    | Lipitor®     |
| Atorvaliq®                   | Livalo®      |
| Caduet®                      | pitavastatin |
| Crestor®                     | Vytorin®     |
| Ezallor® Sprinkle            | Zocor®       |
| fluvastatin / fluvastatin ER | Zypitamag®   |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Patient is clinically stable, and switching would cause a deterioration in condition; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- Quantity limit (all products) = one per day
- **See additional medication-specific criteria below:**

**ATORVALIQ® (ATORVASTATIN)**

- Patient cannot swallow whole tablets;
- Quantity Limit: 20 ml per day

**EZALLOR® SPRINKLE (ROSUVASTATIN)**

- Patient cannot swallow whole tablets

**Duration of Approval:** 1 year

## LITFULO/ RITLECITINIB

**Drug Class:** Janus Kinase (JAK) Inhibitors / TEC family kinase inhibitor

**FDA-approved uses:** Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

**Available dosage forms:** 50mg Capsule

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Severe alopecia areata
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** for up to 1 year
- Prescriber Specialty:** Prescribed by or in consultation with a dermatologist
- Documentation Requirements** (e.g., Labs, Medical Record, Special Studies):
  - Severity of Alopecia Tool (SALT) score of  $\geq 50$  (range: 0 to 100, with 0 representing no scalp hair loss and 100 complete scalp hair loss); **AND**
  - Current AA episode lasting at least 6 months without spontaneous regrowth; **AND**
  - Documentation of inadequate response to a 3-month trial of at least **one** of the following:
    - intralesional corticosteroid therapy; **OR**
    - prescription topical corticosteroid therapy (e.g., betamethasone dipropionate); **OR**
    - systemic immunomodulator therapy (e.g., corticosteroids, methotrexate, cyclosporine)
- Quantity:** 1 capsule per day
- Age:**  $\geq 12$  years of age

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider documentation of clinical improvement in hair regrowth as indicated by improvement in post-treatment SALT score

### **Contraindications/Exclusions/Discontinuation:**

- Not covered for patients with a diffuse hair loss pattern or other forms of alopecia such as androgenetic alopecia (Hamilton-Norwood classification system grade IV or greater) or chemotherapy-induced hair loss
- Cannot be used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants (e.g., methotrexate, azathioprine)

## MACROLIDES

**Drug Class:** Macrolides

**Preferred Agents:** *No Prior Authorization required*

Azithromycin  
Clarithromycin  
erythromycin ethylsuccinate tablets  
erythromycin ethylsuccinate 200mg suspension  
Erythrocin®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

clarithromycin ER  
E.E.S.® tablet, suspension  
EryPed®  
Ery-Tab®  
Erythromycin base  
erythromycin ethylsuccinate 400mg suspension  
Zithromax® tablets, suspension

### **Non-Preferred Agent PA Criteria**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection caused by an organism resistant to the preferred macrolide medications; **OR**
- Therapeutic failure (duration = 3 days) with two preferred medications
- **See additional medication-specific criteria below:**

### **ZITHROMAX (AZITHROMYCIN) 500MG TABLETS**

- **Allow up to 10 tablets per fill for Lyme disease**

### **Quantity Limitations:**

|  |   |
|--|---|
| azithromycin ( <i>Zithromax</i> ®)     | 500mg – 5 per fill<br>600mg – 12 per fill<br>1g packet - 2 per fill |
| clarithromycin tabs ( <i>Biaxin</i> ®) | 28 per fill   |
| Zithromax® ( <i>azithromycin</i> )     | 500mg – 5 per fill<br>600mg – 12 per fill                           |

|  |                        |
|--|------------------------|
|  | 1g packet - 2 per fill |
|--|------------------------|

**Duration of Approval:** Date of service

## MARINOL® / DRONABINOL

**Drug Class:** Antiemetic - Cannabinoids

**FDA-approved uses:**

- Appetite stimulation in AIDS patients
- Chemotherapy-induced nausea and vomiting

**Available dosage forms:** Capsules: 2.5 mg, 5 mg, 10 mg,

**Coverage Criteria/Limitations for initial authorization:**

- Diagnosis:** *chemotherapy induced nausea and vomiting*
- Duration of Approval:**
  - **Initial Authorization:** duration of the chemotherapy treatment
  - **Continuation of Therapy:** limited time -- determined based on the plan of care developed utilizing the chemotherapeutic agents
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must be receiving chemotherapy and meet the following criteria:
    - Intolerant or refractory to first line agents such as Zofran
    - Patient must be under close supervision during the initial use and during dose adjustments due to its potential for altered mental status
    - The number of pills approved will be limited to the amount necessary for a single cycle of chemotherapy.
  - **For antiemetic purposed:** trial and failure, intolerance, or contraindication to an emetic regimen that includes a serotonin antagonist (ondansetron, granisetron), dexamethasone, promethazine, or prochlorperazine
  - **For cancer:** trial and failure, intolerance, or contraindication to an emetic regimen consistent with NCCN guidelines
- Age restrictions:** adults and pediatrics
- Prescriber Specialty:** Oncologist

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Decreased episodes of nausea and vomiting.

**Coverage Criteria/Limitations for initial authorization:**

- Diagnosis:** *appetite stimulation in AIDS patients*
- Duration of Approval:**
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 1 year
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must have AIDS with anorexia associated with weight loss
  - Must have trial and failure, intolerance, or contraindication to megestrol
- Age restrictions:** adults only
- Prescriber Specialty:** Infectious Disease specialist

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Response to treatment with the patient stabilizing one's weight.

**Contraindication/Exclusion/Discontinuation:**

- Hypersensitivity to dronabinol, cannabinoids, sesame oil, or any component of the formulation
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

**Other special considerations:**

- Use cautiously in individuals with the following conditions as they may worsen with use of this product:
  - Seizure
  - Psychiatric disorders
  - Drug Abuse and dependence
  - Cardiovascular disorders.

## MEPRON® / ATOVAQUONE

**Drug Class:** Antiprotozoal Agents - Other

**FDA-approved uses: *Pneumocystis jiroveci* pneumonia:**

- Prophylaxis:** Prevention of *P. jiroveci* pneumonia (PCP) in adults and adolescents 13 years and older who are intolerant to trimethoprim-sulfamethoxazole (TMP-SMZ).
- Treatment:**  
Acute oral treatment of mild to moderate PCP in adults and adolescents 13 years and older who are intolerant to trimethoprim-sulfamethoxazole.

**Available dosage forms:** 750mg/5ml Oral Suspension

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** FDA approved uses as listed above
- Prescriber Specialty:** Infectious Disease
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Failure or contraindication to TMP-SMZ
- Quantity:** 21 day supply
- Age:** 13 years or older
- Route of Administration:** Oral

**Contraindications/Exclusions/Discontinuation:**

- Patient is noncompliant with medical or pharmacologic therapy.
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- Hypersensitivity to atovaquone or any component of the formulation.

## MULTIPLE SCLEROSIS AGENTS

**Drug Class:** Multiple Sclerosis Agents

**Preferred Agents:** *No Prior Authorization required*

Avonex®  
Betaseron® vial / Betaseron® Kit  
Copaxone 20 mg  
dimethyl fumarate (generic for Tecfidera)  
fingolimod (generic for Gilenya)  
Kesimpta®  
teriflunomide (generic for Aubagio)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|   |                         |
|---|-------------------------|
| Aubagio®                                    | Mayzent®                |
| Bafiertam™                                  | Plegridy®               |
| Copaxone® 40 mg                             | Ponvory®                |
| cladribine 10 mg (generic for<br>Mavenclad) | Rebif®/ Rebif Rebidose® |
| glatiramer 20 mg/ml and 40 mg/ml            | Tascenso ODT®           |
| Gilenya®                                    | Tecfidera®              |
| Glatopa®                                    | Vumerity®               |
| Mavenclad®                                  | Zeposia®                |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month with two preferred medications
- **See additional medication-specific criteria below:**

**BAFIERTAM™ (MONOMETHYL FUMARATE)**

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Attestation that Bafiertam will be used as single agent monotherapy
- Quantity limit: 120 per 30 days
- Initial length of authorization: 6 months
- Renewal criteria:
  - Attestation of tolerance to maintenance dose.

- Attestation of a CBC, including lymphocyte count, serum aminotransferase, ALP, and total bilirubin levels

**MAVENCLAD® (CLADRIBINE)**

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include relapsing-remitting disease and active secondary progressive disease; **AND**
- Prescribed by or in consultation with a neurologist
- Therapeutic failure of one-month trial of at least two preferred medications

**MAYZENT® (SIPONIMOD)**

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient CYP2C9 variant status has been tested to determine genotyping (required for dosing); **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

**PLEGRIDY® (PEGINTERFERON BETA-1A)**

- Therapeutic failure of one-month trial of at least two preferred medications required.

**PONVORY® (PONESIMOD)**

- Patient age between 18 years and 55 years; **AND**
- Patient has a diagnosis of a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) or active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Prescriber attestation that first-dose monitoring, as clinically indicated, will occur; **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Prescriber attestation that ponesimod will NOT be used in combination with anti-neoplastic, immunosuppressive, or immune-modulating therapies, or, if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

**TASCENSO ODT® (FINGOLIMOD)**

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Patient age ≥10 years; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient is unable to use generic fingolimod capsules or brand Gilenya capsules due to swallowing difficulties.

**VUMERITY® (DIROXIMEL FUMARATE)**

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

**ZEPOSIA® (OZANIMOD)**

- Patient is 18 Years of age or older; **AND**
- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **OR**
- Diagnosis of moderately or severely active ulcerative colitis (UC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months; **AND**
- For MS, therapeutic failure of one-month trial of at least two preferred MS medications.
- For UC, may bypass PDL criteria.

**Quantity Limitations:**

|            |                 |
|------------|-----------------|
| AVONEX®    | 4 per 34 days   |
| BAFIERTAM® | 120 per 30 days |

**Duration of Approval:** 1 year

# NARCOLEPSY AGENTS

## XYREM / SODIUM OXYBATE

### XYWAV / CALCIUM, MAGNESIUM, POTASSIUM, SODIUM OXYBATE

**Drug Class:** Narcolepsy Agents

**Agents:** *Prior Authorization Criteria below*

Xywav® - Rationale for lower sodium needed for approval of Xywav except when the indication is for idiopathic hypersomnia in adults.

Sodium Oxybate

**FDA-approved uses:** Excessive daytime sleepiness/cataplexy: Treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy; Idiopathic hypersomnia in adults.

**Available dosage forms:** Oral solution, 500 mg per mL

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Type 1 Narcolepsy (cataplexy in narcolepsy)
  - Type 2 Narcolepsy [narcolepsy without cataplexy; excessive daytime sleepiness (EDS) in narcolepsy]
  - Idiopathic hypersomnia (Xywav only)
- Duration of approval:**
  - **Initial authorization:** 3 months
  - **Continuation of Therapy:** for up to 6 months
- Prescriber Specialty:** Board-certified Sleep Medicine Specialist, neurologist, pulmonologist, or psychiatrist. Submit consultation notes if applicable.
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies, Pharmacy claims, Physician attestation):
  - Daily excessive daytime sleepiness for at least 3 months (AASM ICSD-3 Criteria)
  - Nocturnal polysomnography (PSG) confirmation
    - Overnight polysomnography to rule out other conditions and confirm adequate sleep before first Multiple Sleep Latency Test (MSLT)
  - Positive MSLT\* including:
    - Mean Sleep Latency  $\leq$  8 minutes
    - 2 or more sleep onset rapid eye movement (REM) periods  $<$  15 minutes**EXCEPTION** to positive MSLT test for Type 1 Narcolepsy (cataplexy in narcolepsy): Hypocretin-1  $\leq$  110 pg/mL (or  $<$  1/3 of mean normal control values) may be alternative to MSLT sleep study  
**EXCEPTION 2 For Idiopathic Hypersomnia, the number of sleep-onset rapid eye movement sleep periods (SOREMPs) is less than two**
  - Member is not currently on a sedative hypnotic agent (examples include but are not limited to: Lunesta (eszopiclone), Ambien (zolpidem), Sonata (zaleplon), Restoril (temazepam), Halcion (triazolam), or Belsomra (suvorexant))

- **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies, Pharmacy claims, Physician attestation): Continued
  - Member is not currently on other prescription or non-prescription sedatives, including but not limited to excessive alcohol or marijuana use.
  - Metabolic and psychiatric causes have been evaluated and ruled out; if present, attestation that treatment has been optimized.
  - Provider attests that patient is enrolled in the sodium oxybate/Xywav REMS program.
  - **Type 1 Narcolepsy (cataplexy in narcolepsy)**
    - Member has cataplexy defined as more than one episode of generally brief (less than 2 minutes) usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness.
  - **Type 1 Narcolepsy (cataplexy in narcolepsy), continued**
    - Member did not achieve treatment goals or experienced inadequate clinical response after an adherent trial at maximum therapeutic dose, persistent intolerable adverse effects or contraindication to at least ONE (1) medication from **BOTH** of the following: **[BOTH: 1 AND 2]**
      - Non-amphetamine stimulant OR Amphetamine-based stimulant or a methylphenidate-based stimulant:
        - Non-amphetamine stimulant: modafanil (Provigil) or armodafanil (Nuvigil)
        - Amphetamine-based products: amphetamine/dextroamphetamine mixed salts; amphetamine/dextroamphetamine mixed salts extended-release; dextroamphetamine extended-release
        - Methylphenidate-based products: methylphenidate, methylphenidate extended-release, dexmethylphenidate
      - Tricyclic Antidepressants (TCA) OR Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin-norepinephrine Reuptake Inhibitor (SNRI):
        - TCA: imipramine, nortriptyline, protriptyline, clomipramine, etc.
        - SSRI/SNRI: fluoxetine, venlafaxine, atomoxetine, etc.
  - **Type 2 Narcolepsy [narcolepsy without cataplexy]**
    - Other conditions that cause EDS have been ruled out or treated, including (but not limited to): shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, effects of sedating medications, idiopathic hypersomnolence, insufficient sleep at night (sleep deprivation), obstructive sleep apnea, central sleep apnea, periodic limb movement disorder (including restless legs syndrome), depression, Circadian rhythm disorders (including delayed sleep phase syndrome), and sedating medications.
    - Member did not achieve treatment goals or experienced inadequate clinical response after a documented adherent trial at maximum therapeutic dose, persistent intolerable adverse effects or contraindication to at least ONE (1) medication from **ALL** of the following: **[1,2, 3, 4, AND 5]**
      - Non-amphetamine stimulant:
        - Modafanil (Provigil)
        - Armodafanil (Nuvigil)

- **Type 2 Narcolepsy [narcolepsy without cataplexy] continued**
  - Amphetamine-Based Products: amphetamine/dextroamphetamine mixed salts; amphetamine/dextroamphetamine mixed salts extended-release; dextroamphetamine extended-release
  - Methylphenidate based products: methylphenidate, methylphenidate extended release, dexmethylphenidate
  - Dopamine and norepinephrine reuptake inhibitor (DNRI): Sunosi (solriamfetol)
  - Histamine-3 (H3) receptor antagonist/inverse agonist: Wakix (pitolisant)
- Idiopathic Hypersomnia (must meet all):
  - Diagnosis of Idiopathic Hypersomnia
  - Request for Xywav
  - Prescribed by or in consultation with a neurologist or sleep medicine specialist
  - Age  $\geq$  18 years
  - Exclusion of all of the following:
    - Narcolepsy of cataplexy
    - Narcolepsy of EDS
    - Insufficient sleep syndrome

- Quantity:** Maximum Dose: 9 grams per day; 18 mL per day OR 540 mL per 30 days
- Age:**  $\geq$  7 years old and  $>$  20 kg
  - **For idiopathic hypersomnia must be  $\geq$  18 years of age**
- Gender:** Male and Female
- Route of Administration:** Oral

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually
  - Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance), including:
    - Adherent to the prescribed medication regimen
    - Tolerance to therapy
    - No severe adverse reactions or drug toxicity
  - Documentation of efficacy and positive response to therapy as evidenced by response of decreasing cataplexy events and improvement in score for appropriate test (e.g. Epworth Sleepiness Scale, Clinical Global Impression of Change, etc.) for EDS [ALL APPLICABLE]
    - Decrease or reduction in the frequency of cataplexy events/attacks associated with therapy for Type 1 Narcolepsy
    - Decrease or reduction in symptoms of excessive daytime sleepiness associated with therapy
    - For excessive daytime sleepiness (EDS): Improvement in the Epworth Sleepiness Scale (ESS), Clinical Global Impression of Change or Maintenance of Wakefulness Test (MWT) for Type 1 and 2 Narcolepsy
  - A documented attempt to decrease dose or step down to alternative drugs

### **Contraindications/Exclusions/Discontinuation:**

- Non-FDA approved indications
- Hypersensitivity to Xyrem (sodium oxybate) or any ingredient in the formulation
- Co-administration with CNS depressant anxiolytics, sedatives, and hypnotics or other sedative CNS depressant drugs
  - Administration with alcohol or other psychoactive drugs can potentiate the effects of sodium oxybate.
- Co-administration with alcohol (ethanol)
  - Ethanol is contraindicated in patients using sodium oxybate. The combined use of alcohol (ethanol) with sodium oxybate may result in potentiation of the CNS-depressant effects of sodium oxybate and alcohol.
- Succinic Semialdehyde Dehydrogenase Deficiency
  - This rare disorder is an in-born error of metabolism and variably characterized by mental retardation, hypotonia, and ataxia.
- History of drug abuse
  - Sodium oxybate is a CNS depressant with potential for misdirection and abuse and patients should be evaluated for a history of drug abuse.
- Uncontrolled hypertension (due to sodium content)

### **Other special considerations:**

- Patients with Hepatic Impairment Dosing
  - Reduce the initial dosage by 50%

### **References**

1. Xyrem (sodium oxybate) [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; December 2018.
2. Micromedex Healthcare Series. DrugDex. [Micromedex Web site]. Available at: <http://www.thomsonhc.com/micromedex2/librarian> [via subscription only].
3. Drug Facts and Comparisons. Drug Facts and Comparisons 4.0 [online]. 2018. Available from Wolters Kluwer Health, Inc. [via subscription only]
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. URL: <http://www.clinicalpharmacology.com>. [via subscription only]

## NASAL ANTIHISTAMINES

**Drug Class:** Nasal Antihistamines

**Preferred Agents:** *No Prior Authorization required*

azelastine

**Non-Preferred Agents:** *Prior Authorization Criteria below*

olopatadine

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure on one preferred medication

**Duration of Approval:** 1 year

## NASAL CORTICOSTEROIDS

**Drug Class:** Nasal Corticosteroids

**Preferred Agents:** *No Prior Authorization required*

fluticasone (Rx)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Beconase AQ®  
budesonide  
flunisolide  
fluticasone (OTC)  
mometasone spray (RX)  
mometasone 24hr (OTC)  
Nasonex 24hr (OTC)  
Omnaris®  
Qnasl®  
triamcinolone  
Xhance®  
Zetonna®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication
- **See additional medication-specific criteria below:**

**XHANCE® (FLUTICASONE)**

- Diagnosis of chronic rhinosinusitis with or without nasal polyps in adults
- Therapeutic failure with a three-month trial with a preferred medication

**Duration of Approval:** 1 year

## NEUROPATHIC PAIN

**Drug Class:** Neuropathic Pain

**Preferred Agents:** *No Prior Authorization required*

Cymbalta® capsule (\*Carve Out)  
Drizalma Sprinkles® capsule (\*Carve Out)  
duloxetine (generic for Cymbalta) capsule (\*Carve Out)  
duloxetine (generic for Irenka) capsule (\*Carve Out)  
gabapentin capsule, tablet, solution (\*Carve Out)  
gabapentin ER tablet (generic for Gralise®)  
Gabarone® (\*Carve Out)  
Gralise®  
Horizant®  
Lyrica®, Lyrica CR® capsule (\*Carve Out)  
milnacipran HCl (generic for Savella)  
Neurontin® capsule, tablet, solution (\*Carve Out)  
Pregabalin capsule, solution (\*Carve Out)  
Savella® tablet

**LYRICA (PREGABALIN) DOSAGE LIMIT** (\*Carve Out)

- Maximum daily dosage limit = 600 mg across all strengths
- Length of authorization: determined by MDHHS

**Quantity Limitations:**

|                      |   |
|----------------------|---|
| Lyrica® (pregabalin) | 25 mg - 3 per day<br>50 mg - 3 per day<br>75 mg – 3 per day<br>100 mg – 3 per day<br>150 mg – 3 per day<br>200 mg – 3 per day<br>225 mg – 2 per day<br>300 mg – 2 per day<br>20 mg/ml – 20 ml per day |
|----------------------|---|

**Duration of Approval:** 1 year unless otherwise specified

\*Carved Out- Bill Fee-For-Service Medicaid  
(See MPPL @ <https://mi.primetherapeutics.com> for coverage details)

## NON-CF BRONCHIECTASIS AGENTS

**Drug Class:** Platelet Aggregation Inhibitors

**Preferred Agents:** *No Prior Authorization required*

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Brinsupri (brensocatib) tablet

### **Non-Preferred Agent PA Criteria:**

#### **Initial Request**

- Patient is 12 years of age or older; **AND**
- Prescriber attests to diagnosis of non-cystic fibrosis bronchiectasis (NCFB) confirmed by high-resolution computed tomography (HRCT) of the chest performed within the previous 12 months; **AND**
- Prescriber attests to at least 1 pulmonary exacerbation (PEs) for patients 12 - 17 years of age or at least 2 PEs if  $\geq$  18 years of age) in the past 12 months requiring an antibiotic prescription; **AND**
- Prescribed by or in consultation with a pulmonologist or infectious disease specialist; **AND**
- Prescriber confirms the patient is a current non-smoker (CDC-defined smoker: a person who has smoked 100 cigarettes in their lifetime and who currently smokes); **AND**
- Patient's diagnosis must **exclude** cystic fibrosis, alpha-1 antitrypsin deficiency, primary diagnosis of COPD, primary diagnosis of asthma

#### **Renewal Request**

- Prescriber attests that patient has experienced a positive response to therapy. (such as a reduction in the number of exacerbations, preservation of lung function, reduced cough, reduced sputum production)

**Quantity Limits:** 30 tablets per 30 days

**Duration of Approval:** 1 year

## NON-STEROIDAL ANTI-INFLAMMATORY – COX II INHIBITORS

**Drug Class:** Non-Steroidal Anti-Inflammatory – Cox II Inhibitors

**Preferred Agents:** *No Prior Authorization required*

celecoxib

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Celebrex®  
Vyscoxa

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; OR
- Contraindication or drug to drug interaction with the preferred medications; OR
- History of unacceptable side effects; OR
- Therapeutic failure of one month each with two preferred NSAIDS
- See additional medication-specific criteria below:

**CELEBREX® (CELECOXIB)**

- Therapeutic failure of one month each with two preferred NSAIDS (unless clinically contraindicated), including generic celecoxib.

**VYSCOXA® (CELECOXIB) SUSPENSION**

- Patient has difficulty swallowing: AND
- Therapeutic failure of a 30-day trial each with two or more oral liquid or chewable NSAIDS

**QUANTITY LIMITS**

|                                       |               |
|---------------------------------------|---------------|
| Celebrex 50mg, 100mg, 200mg capsules  | 2 per day     |
| Celebrex 400mg                        | 2 per day     |
| celecoxib 50mg, 100mg, 200mg capsules | 2 per day     |
| celecoxib 400mg                       | 2 per day     |
| Vyscoxa Suspension                    | 40 mL per day |

**Duration of Approval:** For the duration of the prescription up to 1 year

## NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

**Drug Class:** Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)

**Preferred Agents:** *No Prior Authorization required*

diclofenac  
diclofenac topical gel 1% (generic Voltaren Gel®)  
diclofenac topical gel 1% (OTC)  
diclofenac topical solution 1.5%  
ibuprofen  
indomethacin  
ketorolac tablets  
meloxicam tablets  
nabumetone  
naproxen OTC  
naproxen (generic for Naprosyn®)  
sulindac

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|  |  |
|--|--|
| Arthrotec®                             | Lofena®                                    |
| Daypro®                                | Lurbiro®                                   |
| diclofenac ER                          | meclofenamate sodium                       |
| diclofenac epolamine 1.3% patch        | mefenamic acid                             |
| diclofenac-misoprostol                 | meloxicam capsules                         |
| diclofenac potassium                   | Nalfon®                                    |
| diclofenac 2% pump (generic Pennsaid)  | Naprelan CR®                               |
| diflunisal                             | Naprosyn Suspension®                       |
| Dolobid®                               | naproxen (generic for Anaprox)             |
| dual action pain (OTC -ibuprofen/apap) | naproxen delayed release                   |
| EC-naproxen                            | naproxen/esomeprazole (generic for Vimovo) |
| etodolac / etodolac ER                 | naproxen suspension                        |
| Feldene®                               | oxaprozin                                  |
| fenoprofen                             | Pennsaid®                                  |
| flurbiprofen                           | piroxicam                                  |
| ibuprofen 300 mg tablet                | Relafen DS®                                |
| ibuprofen-famotidine                   | Tolectin®                                  |
| indomethacin ext release, oral susp    | tolmetin sodium                            |
| ketoprofen ext release                 | Vimovo®                                    |
| ketoprofen immediate release           |  |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one month each with two preferred medications
- **See additional medication-specific criteria below:**

**ibuprofen 300 mg tablet**

- Prescriber will need to justify medical necessity of unique strength
- Length of approval: For the duration of the prescription up to 1 year

**VIMOVO® (NAPROXEN/ESOMEPRAZOLE) AND DUEXIS® (IBUPROFEN/FAMOTIDINE)**

- History of or active GI bleed/ulcer OR
- Risk for bleed/ulcer –
- Therapeutic failure with one preferred medication

**Quantity Limitations:**

|                                       |             |
|---------------------------------------|-------------|
| <i>diclofenac transdermal patch</i>   | 2 per day   |
| Toradol® ( <i>ketorolac</i> ) tablets | 21 per fill |

**Duration of Approval:** For the duration of the prescription up to 1 year, unless otherwise noted in Medication-Specific Information

## OHTUVAYRE (ENSIFENTRINE)

**Drug Class** (ETC\_Name): Respiratory Phosphodiesterase 3 and 4 (PDE3 and PDE4) Inhibitors

**FDA-approved uses:** Indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients

**Available dosage forms:** 3 mg/2.5 mL ampule (nebulizer solution) - 60 ampules per carton

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** moderate to severe chronic obstructive pulmonary disease (COPD)
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** for up to 12 months
- Prescriber Specialty:** Prescribed by or in consultation with a pulmonologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Spirometry demonstrating FEV1/FVC ratio <0.7; **AND**
  - Post-bronchodilator FEV1 ≥30% and ≤ 80% of predicted normal; **AND**
  - Modified Medical Research Council (mMRC) dyspnea score of ≥ 2 **OR** COPD Assessment Test (CAT) score of ≥ 10; **AND**
  - Patient had inadequate response after a 3-month trial of either a LAMA/LABA dual-maintenance therapy or LAMA/LABA/ICS triple-maintenance therapy; **AND**
  - Patient will continue LAMA/LABA dual therapy or LAMA/LABA/ICS triple therapy in combination with Ohtuvayre unless not tolerated or contraindicated; **AND**
  - Member does not have a diagnosis of asthma; **AND**
  - Prescriber attests Ohtuvayre will not be used in combination with roflumilast
- Quantity:** 150 mL (60 ampules) / 30 days
- Age:** Patient is 18 years of age or older
- Route of Administration:** Nebulized oral inhalation

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Must demonstrate a decrease in symptoms and/or COPD exacerbations vs baseline; **AND**
  - Continue use of dual or triple therapy that includes (LABA/LAMA) in conjunction with Ohtuvayre **AND**
  - Prescriber attests Ohtuvayre will not be used in combination with roflumilast

## OPHTHALMIC ANTI-INFLAMMATORY/IMMUNOMODULATOR/DRY EYE

**Drug Class:** Ophthalmic Anti-Inflammatory/Immunomodulator

**Preferred Agents:** *No Prior Authorization required*

Restasis® single-use vials  
Xiidra®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|                                  |                       |
|----------------------------------|-----------------------|
| Cequa®                           |                       |
| cyclosporine (generic Restasis®) | Tryptyr® (acoltremon) |
| Eysuvis®                         | Tyrvaya®              |
| Miebo®                           | Verkazia®             |
| Restasis® multidose vials        | Vevye®                |

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a six-week trial with one preferred medication; **AND**
- **See additional medication-specific criteria below:**

**EYSUVIS® (LOTEPREDNOL):**

- For Renewal: Patient has had an examination under magnification (e.g., slit lamp) and evaluation of the intraocular pressure (IOP)
- Renewal length of approval: 2 weeks

**MIEBO® (PERFLUOROHEXYLOCTANE/PF)**

- Patient is 18 years of age or older; **AND**
- **Quantity Limit:** 3.0 mls per 30 days

**TRYPTYR® (ACOLTREMON)**

- Patient is 18 years of age or older; **AND**
- **Quantity Limit:** 60 single dose vials (one vial can be used to dose both eyes) 30 days

**VERKAZIA® (CYCLOSPORINE):** (PDL criteria do not apply)

- Patient is ≥4 years of age; **AND**
- Diagnosis of moderate to severe vernal keratoconjunctivitis; **AND**
- Trial and failure, contraindication, or intolerance to one of the following:

- Topical ophthalmic “dual-action” mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine) **OR**
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn); **AND**
- Prescribed by or in consultation with an ophthalmologist or optometrist.

**VEVYE® (CYCLOSPORINE)**

- Patient is 18 years of age or older; **AND**
- Quantity Limit: 2 ml per 30 days

**QUANTITY LIMITS**

|   |   |
|---|---|
| Restasis (cyclosporine) single-use containers | 60 per 30 days  |
| Restasis multi-dose vial                      | 5.5ml (1 vial) per 30 days  |
| Xiidra  | 60 single-use containers per 30 days                                  |
| Cequa   | 60 single-use containers per 30 days                                  |
| Eysuvis                                       | 8.3ml (1 bottle) per 14 days  |
| Miebo   | 3ml per 30 days   |
| Tryptyr                                       | 60 single dose vials (one vial can be used to dose both eyes) 30 days |
| Tyrvaya                                       | 8.4ml (2 bottles) per 30 days   |
| Verkazia                                      | 120 single-dose vials per 30 days                                     |
| Vevye   | 2ml per 30 days   |

**Duration of Approval:** 1 year (except Eysuvis – 2 weeks)

## OPHTHALMIC ANTIHISTAMINES

**Drug Class:** Ophthalmic Antihistamines

**Preferred Agents:** *No Prior Authorization required*

azelastine  
ketotifen fumarate (OTC Only)  
olopatadine (OTC Only)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

alcaftadine  
Alrex®  
bepotastine  
Bepreve®  
epinastine  
Lastacaft®  
loteprednol (generic for Alrex)  
olopatadine RX  
Pataday®  
Zaditor®  
Zerviate®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

**Duration of Approval:** 1 year

## OPHTHALMIC FLUOROQUINOLONES

**Drug Class:** Ophthalmic Fluoroquinolones

**Preferred Agents:** *No Prior Authorization required*

ciprofloxacin  
moxifloxacin (generic for Vigamox®)  
ofloxacin

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Besifloxacin (generic for Besivance)  
Besivance®  
Ciloxan® 0.3% Oint. (G)  
gatifloxacin  
levofloxacin  
moxifloxacin (generic for Moxeza®)  
Ocuflox®  
Vigamox®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication

**Duration of Approval:** 1 year

## OPHTHALMIC MACROLIDES

**Drug Class:** Ophthalmic Macrolides

**Preferred Agents:** *No Prior Authorization required*

erythromycin 0.5% eye ointment

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Azasisite® eye drops

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Therapeutic failure with one preferred medication

**Duration of Approval:** 1 year

## OPHTHALMIC MAST CELL STABILIZERS

**Drug Class:** Ophthalmic Mast Cell Stabilizers

**Preferred Agents:** *No Prior Authorization required*

cromolyn sodium

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Alomide®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with one preferred medication

**Duration of Approval:** 1 year

## OPHTHALMIC NSAIDS

**Drug Class:** Ophthalmic NSAIDS

**Preferred Agents:** *No Prior Authorization required*

diclofenac  
flurbiprofen  
ketorolac

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Acular®  
Acular LS®  
Acuvail®  
bromfenac  
bromfenac (generic for Bromsite®)  
bromfenac (generic for Prolensa®)  
Bromsite®  
Ilevro®  
ketorolac LS  
Nevanac®  
Prolensa®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Medical necessity of lower strength dosages for post-operative pain relief; **OR**
- Therapeutic failure with a trial with one preferred medication

**Duration of Approval:** 1 year

## OPIOIDS – LONG ACTING

**Drug Class:** Opioids – Long Acting

**Preferred Agents:** *Clinical Prior Authorization for codeine and tramadol containing products only.*

morphine sulfate ER tablets  
 Oxycontin®  
 tramadol ER tablets

**Preferred Agent PA Criteria:**

≥ 12 years of age (for codeine and tramadol containing products only)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Belbuca®  
 Conzip ER®  
 Diskets  
 hydrocodone ER capsules (generic Zohydro ER®)  
 hydrocodone ER tablets (generic Hysingla ER®)  
 hydromorphone ER®  
 Hysingla ER®  
 Methadone

Methadose tablet dispersible, oral concentrate  
 morphine sulfate ER caps (generic Avinza®)  
 morphine sulfate ER caps (generic Kadian®)  
 MS Contin®  
 oxycodone ER  
 oxymorphone ER  
 tramadol ER capsules

**Non-Preferred Agent PA Criteria:**

- ≥ 12 years of age (for codeine and tramadol containing products only) **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one week with one preferred medication
- **See additional medication-specific criteria below:**

**BELBUCA® (BUPRENORPHINE BUCCAL FILM)**

- Diagnosis of moderate to severe chronic pain requiring around the clock opioid analgesia; **AND**
- Patient ≥ 18 years old

**Quantity Limitations:**

|   |                 |
|---|-----------------|
| Belbuca® ( <i>buprenorphine</i> )                               | 60 per 30 days  |
| Oxycontin® ER 10mg ( <i>oxycodone-controlled release tab</i> )  | 180 per 30 days |
| Oxycontin® ER 15mg ( <i>oxycodone-controlled release tab</i> )  | 120 per 30 days |
| Oxycontin® ER 20 mg ( <i>oxycodone-controlled release tab</i> ) | 90 per 30 days  |
| Oxycontin® ER 30mg ( <i>oxycodone-controlled release tab</i> )  | 60 per 30 days  |
| Oxycontin® ER 40mg ( <i>oxycodone-controlled release tab</i> )  | 45 per 30 days  |
| Oxycontin® ER 60 mg ( <i>oxycodone-controlled release tab</i> ) | 30 per 30 days  |
| Oxycontin® ER 80mg ( <i>oxycodone-controlled release tab</i> )  | 22 per 30 days  |

**Duration of Approval:** 6 months for Zohydro® ER; 1 year for all other medications

**\*Note:** High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

**Initial High MME Exceptions:** If any are “True”, no further information is required and member meets the requirements for this section. If all are “False” then proceed to the remaining requirements under Additional High MME Criteria.

1. Does the patient have documented “current” cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

**Additional High MME Criteria:**

- **Provider must attest to all of the following:**
  - Risk assessment has been performed
  - Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
  - MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber’s assessment the drugs and doses are safe for the member.
  - Concurrently prescribed drugs have been reconciled and reviewed for safety
  - The following Non-opioid pain interventions have been recommended and/or utilized:
    - Non-opioid medications
    - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
  - A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
  - Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
  - If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).
- **Additional documentation:**
  - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
  - Recent non-opioid medications utilized for pain management or rationale these cannot be used
  - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
  - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
    - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: [CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR](#)
    - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

**Criteria for Continuation of Therapy:**

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

## OPIOIDS – SHORT AND INTERMEDIATE ACTING

**Drug Class:** Opioids – Short and Intermediate Acting

**Preferred Agents:** *Clinical Prior Authorization for codeine and tramadol containing products only.*

codeine  
codeine / acetaminophen  
Endocet  
hydrocodone / acetaminophen  
hydromorphone oral tablets  
morphine sulfate tablets, solution, suppository  
oxycodone tabs (5mg, 10mg, 15mg)  
oxycodone oral solution  
oxycodone / acetaminophen  
tramadol / acetaminophen  
tramadol

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|   |   |
|---|---|
| butorphanol                                   | oxycodone capsule                           |
| codeine / acetaminophen /caffeine /butalbital | oxycodone tabs (20mg, 30mg)                 |
| codeine / aspirin /caffeine /butalbital       | oxycodone oral conc soln                    |
| Dilaudid® all forms                           | oxymorphone                                 |
| fentanyl citrate buccal                       | pentazocine/naloxone                        |
| Fioricet w/ Codeine®                          | Percocet®                                   |
| hydrocodone/ ibuprofen                        | Prolate®                                    |
| hydromorphone suppository                     | Roxicodone®                                 |
| levorphanol                                   | RoxyBond®                                   |
| meperidine tablets, solution                  | Seglentsis®                                 |
| Nalocet®                                      | tramadol oral solution (generic Qdolo Soln) |

**Preferred Agent PA Criteria:**

- ≥ 12 years of age (for codeine and tramadol containing products only) **AND**

### **SHORT ACTING OPIOID 7-DAY LIMIT**

Claims submitted for short acting opioids for more than a 7-day supply for opioid naïve patients (i.e., those with no claim for an opioid medication within the past 180 days) will deny for prior authorization.

**Non-Preferred Agent PA Criteria:**

- ≥ 12 years of age (for codeine and tramadol containing products only) **AND**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one week each with two preferred medications
- **See additional medication-specific criteria below:**

**SHORT ACTING OPIOID 7-DAY LIMIT**

Claims submitted for short acting opioids for more than a 7-day supply for opioid naïve patients (i.e., those with no claim for an opioid medication within the past 180 days) will deny for prior authorization.

**FENTANYL – ORAL (ABSTRAL®)**

- Management of breakthrough cancer pain in patients established on immediate release and long-acting opioid therapy.
- Requests for controlled substances must be under the name and ID of the prescribing physician.
- > 18 years of age
- Medication must be prescribed by a physician who is experienced in the use of Schedule II opioids
- Current dosage regimen of the long acting and regularly prescribed immediate release opioids must be maximally optimized.
- No concomitant use of other inducers of cytochrome P450
- No concomitant use of other inhibitors of cytochrome P450

**ROXYBOND® (OXYCODONE) TABLETS**

- PDL criteria may be bypassed to allow coverage if an abuse deterrent formulation is needed

**SEGLENTIS (CELECOXIB/TRAMADOL)**

- Patient age is 12 years and older; **AND**
- Prescriber attests that Seglentis will not be used for postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; **AND**
- Quantity Limit=120 tablets per 30 days

**TRAMADOL (QDOLO®) ORAL SOLUTION**

- Patient age is 12 years and older; **AND**
- Allow if patient has difficulty swallowing tablets
- Quantity limit = 80 ml per day (400mg/day)

**Quantity Limitations:**

|                                     |                                     |
|-------------------------------------|-------------------------------------|
| FENTANYL CITRATE                    | 120 units/30 days for each strength |
| BUTORPHANOL 10MG/ML NASAL SPRAY     | 15 mL per 30 days                   |
| CODEINE SULFATE 15 MG TAB           | 180 per 30 days                     |
| CODEINE SULFATE 30MG TAB            | 180 per 30 days                     |
| CODEINE SULFATE 60 MG TAB           | 180 per 30 days                     |
| HYDROMORPHONE HCL 1 MG/ML ORAL CONC | 120ml per 30 days                   |

**Quantity Limitations: continued**

|                           |                 |                          |
|---------------------------|-----------------|--------------------------|
| HYDROMORPHONE HCL 2MG TAB | 180 per 30 days | 199                      |
| HYDROMORPHONE HCL 4MG TAB | 135 per 30 days | Effective Date: 5/1/2026 |

|                                       |                    |
|---------------------------------------|--------------------|
| HYDROMORPHONE HCL 8MG TAB             | 67 per 30 days     |
| MEPERIDINE HCL 50MG TAB               | 120 per 30 days    |
| MEPERIDINE HCL 50 MG/5ML SOLN         | 240ml per 30 days  |
| MORPHINE SULFATE 10 MG /5ML SOLN      | 240ml per 30 days  |
| MORPHINE SULFATE 100 MG/5ML SOLN      | 120 per 30 days    |
| MORPHINE SULFATE 10 MG/0.5ML ORAL SYR | 120 per 30 days    |
| MORPHINE SULFATE 20 MG/ML ORAL SYR    | 120 per 30 days    |
| MORPHINE SULFATE 15 MG TAB            | 180 per 30 days    |
| MORPHINE SULFATE 20 MG/5ML SOLN       | 240ml per 30 days  |
| MORPHINE SULFATE 30 MG TAB            | 90 per 30 days     |
| OXYCODONE HCL 5 MG CAP                | 90 per 30 days     |
| OXYCODONE HCL 5MG TAB                 | 90 per 30 days     |
| OXYCODONE HCL 5MG/5ML SOLN            | 240ml per 30 days  |
| OXYCODONE HCL 20MG/ML SOLN            | 90ml per 30 days   |
| OXYCODONE HCL 10MG TAB                | 90 per 30 days     |
| OXYCODONE HCL 15 MG TAB               | 90 per 30 days     |
| OXYCODONE HCL 20 MG TAB               | 90 per 30 days     |
| OXYCODONE HCL 30 MG TAB               | 60 per 30 days     |
| OXYMORPHONE HCL 5MG TAB               | 120 per 30 days    |
| OXYMORPHONE HCL 10MG TAB              | 90 per 30 days     |
| ROXYBOND 5MG TAB                      | 90 per 30 days     |
| ROXYBOND 10MG TAB                     | 90 per 30 days     |
| ROXYBOND 15MG TAB                     | 90 per 30 days     |
| ROXYBOND 30MG TAB                     | 60 per 30 days     |
| SEGLENTIS 56 MG - 44 MG TAB           | 120 per 30 days    |
| TRAMADOL SOLUTION 25MG/5ML (QDOLO)    | 80 per day (400mg) |

**Duration of Approval:** 1 year

**Chronic Opioid Management with High Morphine Milligram Equivalents (MME)**

\***Note:** High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

**Initial High MME Exceptions:** If any are “True”, no further information is required and member meets the requirements for this section. If all are “False” then proceed to the remaining requirements under *Additional High MME Criteria.*

1. Does the patient have documented “current” cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

**Additional High MME Criteria:**

- **Provider must attest to all of the following:**
  - Risk assessment has been performed

- Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
  - MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber's assessment the drugs and doses are safe for the member.
  - Concurrently prescribed drugs have been reconciled and reviewed for safety
  - The following Non-opioid pain interventions have been recommended and/or utilized:
    - Non-opioid medications
    - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
  - A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
  - Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
  - If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).
- **Additional documentation:**
    - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
    - Recent non-opioid medications utilized for pain management or rationale these cannot be used
    - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
    - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
      - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: [CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR](#)
      - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

**Criteria for Continuation of Therapy:**

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

## OPIOIDS – TRANSDERMAL

**Drug Class:** Opioids – Transdermal

**Preferred Agents:** *No Prior Authorization required*

Butrans® patches  
fentanyl patches 12, 25, 50, 75, and 100 mcg only (generic only)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

buprenorphine patches  
fentanyl generic patches 37.5 mcg, 62.5 mcg and 87.5 mcg only

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medication; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure of one week with one preferred medication

**Quantity Limitations:**

|   |               |
|---|---------------|
| Butrans® ( <i>buprenorphine patch</i> ) | 4 per 28 days |
| fentanyl patch (Duragesic®)             | 10 per fill   |

**Duration of Approval:** 1 year

### **Chronic Opioid Management with High Morphine Milligram Equivalents (MME)**

\***Note:** High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

**Initial High MME Exceptions:** If any are “True”, no further information is required and member meets the requirements for this section. If all are “False” then proceed to the remaining requirements under Additional High MME Criteria.

1. Does the patient have documented “current” cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

**Additional High MME Criteria:**

- **Provider must attest to all of the following:**
  - Risk assessment has been performed
  - Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
  - MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber's assessment the drugs and doses are safe for the member.
  - Concurrently prescribed drugs have been reconciled and reviewed for safety
  - The following Non-opioid pain interventions have been recommended and/or utilized:
    - Non-opioid medications
    - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
  - A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
  - Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
  - If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).
- **Additional documentation:**
  - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
  - Recent non-opioid medications utilized for pain management or rationale these cannot be used
  - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
  - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
    - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: [CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR](#)
    - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

**Criteria for Continuation of Therapy:**

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

## ORAL HYPOGLYCEMICS – 2<sup>ND</sup> GENERATION SULFONYLUREAS

**Drug Class:** Oral Hypoglycemics – 2nd Generation Sulfonylureas

**Preferred Agents:** *No Prior Authorization required*

glimepiride  
glipizide / glipizide ER  
glyburide  
glyburide micronized

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Glucotrol XL<sup>®</sup>

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – ALPHA-GLUCOSIDASE INHIBITORS

**Drug Class:** Oral Hypoglycemics – Alpha-Glucosidase Inhibitors

**Preferred Agents:** *No Prior Authorization required*

acarbose  
miglitol

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Precose®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – BIGUANIDES

**Drug Class:** Oral Hypoglycemics – Biguanides

**Preferred Agents:** *No Prior Authorization required*

metformin / metformin XR

**Non-Preferred Agents:** *Prior Authorization Criteria below*

metformin 625mg, 750mg tablets  
metformin ER (generic for Fortamet)  
metformin (generic for Glumetza)  
metformin solution (generic for Riomet)  
Riomet®  
Riomet ER®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – COMBINATIONS

**Drug Class:** Oral Hypoglycemics – Combinations

**Preferred Agents:** *No Prior Authorization required (except for agents containing DPP-4 indicated with \*)*  
 glyburide / metformin  
 \*Janumet®/\*Janumet XR®  
 \*Jentadueto®/ \*Jentadueto XR®  
 Synjardy®/ Synjardy XR®  
 Xigduo XR®

**Clinical PA Criteria For Preferred Agents That Contain A DPP-4 Inhibitor (indicated by leading \*):**

- Discontinuation of GLP-1 agonists

**Non-Preferred Agents:** *Prior Authorization Criteria below (Agents That Contain A DPP-4 Inhibitor (indicated by leading \*))*

|  |   |
|--|---|
| Actoplus Met®<br>*alogliptin/metformin<br>*alogliptin/pioglitazone<br>dapagliflozin/metformin ER<br>Duetact®<br>glipizide/metformin<br>*Glyxambi®<br>Invokamet®/Invokamet XR®<br>*Kazano®<br>*linagliptin and metformin<br>hydrochloride | *Oseni®<br>pioglitazone/glimepiride<br>pioglitazone/metformin<br>*Qtern®<br>*saxagliptin/metformin ER<br>*sitagliptin/metformin<br>*sitagliptin/metformin ER<br>Segluromet®<br>*Steglujan®<br>*Trijardy XR<br>*Zituvimet®/Zituvimet XR® |
|--|---|

**Non-Preferred Agent PA Criteria:**

- Discontinuation of GLP-1 agonists (Only applies to products that contain a DPP-4 inhibitor); **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

**QUANTITY LIMITS**

|                                    |                   |
|------------------------------------|-------------------|
| Janumet® (sitagliptin / metformin) | 2 tablets per day |
|------------------------------------|-------------------|

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – DPP4 INHIBITORS

**Drug Class:** Oral Hypoglycemics – DPP4 Inhibitors

**Preferred Agents:** *Clinical Prior Authorization below*

Januvia®  
Tradjenta®

**Clinical Preferred Agent PA Criteria:**

- Discontinuation of GLP-1 agonists

**Non-Preferred Agents:** *Prior Authorization Criteria below*

alogliptin  
Brynovin® (sitagliptin)  
Nesina®  
saxagliptin  
sitagliptin (generic for Zituvio®)  
Zituvio®

**Non-Preferred Agent PA Criteria:**

- Discontinuation of GLP-1 agonists; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class
- **See additional medication-specific criteria below:**

**Clinical PA Criteria applies to Listed Agents Below**

**BRYNOVIN® (SITAGLIPTIN)**

- Patient has difficulty swallowing

### QUANTITY LIMITS

|                                  |   |
|----------------------------------|---|
| Brynovin® (sitagliptin)          | 4ml/day   |
| Januvia® (sitagliptin phosphate) | 100mg/day max daily dose limit; quantity limit of 1 tablet – any strength per day |
| TRADJENTA 5 MG TABLET            | 5mg per day   |

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – MEGLITINIDES

**Drug Class:** Oral Hypoglycemics – Meglitinides

**Preferred Agents:** *No Prior Authorization required*

nateglinide  
repaglinide

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – SGLT2 INHIBITORS

**Drug Class:** Oral Hypoglycemics – SGLT2 Inhibitors

**Preferred Agents:** *No Prior Authorization required*

Farxiga®  
Jardiance®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

dapagliflozin  
Inpefa®  
Invokana®  
Steglatro®

**Non-preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

**Duration of Approval:** 1 year

## ORAL HYPOGLYCEMICS – THIAZOLIDINEDIONES

**Drug Class:** Oral Hypoglycemics – Thiazolidinediones

**Preferred Agents:** *No Prior Authorization required*

pioglitazone

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Actos®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with a preferred medication

**Duration of Approval:** 1 year

## ORLYNVAH (SULOPENEM ETZADROXIL AND PROBENECID)

**Drug Class:** Penem antibacterial-renal tubular transport inhibitor combination

**FDA-approved uses:** Treatment of uncomplicated urinary tract infections (uUTI) caused by the designated microorganisms *Escherichia Coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis* in adult women who have limited or no alternative oral antibacterial options.

**Available dosage forms:** Tablet 500mg-500mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** uUTI caused by the designated microorganisms listed above
- Duration of approval:**
  - 5 days
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient is female and 18 years of age or older.
  - Patient has diagnosis of uncomplicated urinary tract infection (uUTI) caused by *Escherichia Coli*, *Klebsiella pneumoniae*, or *Proteus mirabilis*.
  - Patient has limited or no alternative ORAL antibacterial treatment options.
  - Provider submits documented culture demonstrating the uUTI is caused by bacteria with sensitivity to sulopenem or ertapenem AND resistance to all alternatives such as TMP-SMX, nitrofurantoin, fosfomycin, penicillins, cephalosporins, fluoroquinolones, unless contraindicated.
- Quantity:** 10 tablets per 5 days
- Age:** >= 18 years
- Gender:** Female
- Route of Administration:** Oral

**Contraindications/Exclusions/Discontinuation:**

- The diagnosis must **exclude** cUTI, or as step-down treatment after IV antibacterial treatment of cUTI, or UTI caused by non-designated microorganisms

## OSTEOPOROSIS AGENTS: BISPHOSPHONATES

**Drug Class:** Osteoporosis Agents: Bisphosphonates

**Preferred Agents:** *No Prior Authorization required*

alendronate sodium

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Actonel®  
alendronate sodium oral solution  
Atelvia®  
Binosto®  
Boniva®  
Fosamax®  
Fosamax Plus D®  
Ibandronate  
risedronate (Actonel)  
risedronate (Atelvia)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- See additional medication-specific criteria below:

**Quantity Limitations:**

|  |                      |
|--|----------------------|
| Atelvia® (risedronate) – brand & generic | 4 per 30 days        |
| Actonel® (risedronate)                   | 35mg - 4 per 28 days |

**Duration of Approval:** 1 year

## OSTEOPOROSIS AGENTS: OTHER

**Drug Class:** Osteoporosis Agents: Other

**Preferred Agents:** *No Prior Authorization required (except for agents listed under Clinical PA Criteria)*

calcitonin nasal spray  
Forteo®

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Bonsity (teriparatide)  
teriparatide  
Tymlos®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- **See additional medication-specific criteria below:**

**Clinical PA Criteria applies to Listed Agents Below**

**BONSITY® (TERIPARATIDE)**

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures
- Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Length of authorization: maximum cumulative duration of 2 years per lifetime, unless clinical documentation is provided showing patient remains at or has returned to having a high risk for fracture

**FORTEO® (TERIPARATIDE)**

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures
- Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

- Length of authorization: maximum cumulative duration of 2 years per lifetime, unless clinical documentation is provided showing patient remains at or has returned to having a high risk for fracture

**TYMLOS® (ABALOPARATIDE) – PDL CRITERIA DOES NOT APPLY**

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures; **OR**
- Treatment of osteoporosis in men who are at high risk for fractures
- Length of authorization: maximum cumulative duration of 2 years per lifetime (includes any prior use of Forteo)

**Duration of Approval:** 1 year (Forteo and Tymlos – maximum 2 years per lifetime)

## OSTEOPOROSIS AGENTS: SERMs

**Drug Class:** Osteoporosis Agents: SERMs

**Preferred Agents:** *No Prior Authorization required*

raloxifene

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Evista®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications

**Duration of Approval:** 1 year

## OTIC ANTIBIOTICS

**Drug Class:** Otic Antibiotics

**Preferred Agents:** *No Prior Authorization required*

ciprofloxacin-dexamethasone (generic for Ciprodex®)  
neomycin-polymyxin-HC ear soln/susp  
ofloxacin otic

**Non-Preferred Agents:** *Prior Authorization Criteria below*

ciprofloxacin otic  
ciprofloxacin-fluocinolone (generic for Otovel®)  
ciprofloxacin-hydrocortisone (generic for Cipro HC ®)  
Cipro HC®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure (duration = 3 days) with one preferred medication

**Duration of Approval:** 1 year for all other medications

## OTIC QUINOLONES

**Drug Class:** Otic Quinolones

**Preferred Agents:** *No Prior Authorization required*

Ciprodex®  
ciprofloxacin-dexamethasone (generic for Ciprodex®)  
ofloxacin otic

**Non-Preferred Agents:** *Prior Authorization Criteria below*

ciprofloxacin otic  
ciprofloxacin-fluocinolone (generic for Otovel®)  
Cipro HC®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure (duration = 3 days) with one preferred medication

**Duration of Approval:** 1 year for all other medications

## OXAZOLIDINONES

**Drug Class:** Oxazolidinones

**Preferred Agents:** *No Prior Authorization required*

Linezolid tablets

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Linezolid suspension  
Sivextro®  
Zyvox®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medication
- Contraindication or drug to drug interaction with the preferred medication
- History of unacceptable side effects
- **See additional medication-specific criteria below:**

**SIVEXTRO® (TEDIZOLID PHOSPHATE)**

For diagnosis of non-purulent cellulitis

- Trial, failure or intolerance to first line beta lactam therapy **and**
- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (SMZ/TMP), tetracycline (minocycline or doxycycline) **or**
- Culture and *sensitivity* results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

For diagnosis of purulent cellulitis, abscess, or wound infection:

- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (smz/tmp), tetracycline (minocycline or doxycycline) **or**
- Culture and sensitivity results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

**Quantity Limitations:**

|                                  |             |
|----------------------------------|-------------|
| Linezolid tabs ( <i>Zyvox</i> ®) | 28 per fill |
| Sivextro® (tedizolid)            | 14 per fill |
| Zyvox® tabs ( <i>linezolid</i> ) | 28 per fill |

**Duration of Approval:** 2 months

## OXBRYTA® / VOXELOTOR

**Drug Class:** Sickle Hemoglobin (HbS) Polymerization Inhibitor

**FDA-approved uses:** sickle-cell disease

**Available dosage forms:** 300mg and 500mg Tablet, 300mg Tablet for Suspension

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** sickle-cell disease
- Duration of approval:**
  - **Initial authorization:** 12 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:** Prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Baseline hemoglobin level between 5.5 g/dL and 10.5g/dL **AND**
- Age:**
  - Oxbryta 300mg tablet: ≥ 4 years of age
  - Oxbryta 500mg tablet: ≥ 12 years of age
  - Oxbryta 300mg tablet for suspension: ≥ 4 years of age
- Quantity:** 90 tablets/30 days
- Route of Administration:** oral
- Place of Service:** outpatient

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Patient must show an increase in hemoglobin level from initial baseline **OR**
  - Provider attests to other positive clinical response

## OXERVATE™ (CENEGERMIN-BKBJ)

**Drug Class:** Recombinant human nerve growth factor (rhNGF)

**FDA-approved uses:** Indicated for the treatment of neurotrophic keratitis

**Available dosage forms:** Ophthalmic solution, 0.002% (per mL)

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** FDA approved indications as listed above
- Duration of approval:**
  - **Initial authorization:** 56 days
- Prescriber Specialty:** Prescribed by, or in consultation with, an ophthalmologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Attestation that the patient or caregiver has been counseled on proper administration technique
  - Documentation that the member has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in affected eye(s)
  - Documentation that the member has tried and failed at least two conventional non-surgical treatments (e.g. preservative-free artificial tears, lubricant eye ointment, topical antibiotic eye drops, therapeutic contact lenses)
- Quantity:** 28 vials every 28 days for the treatment of one eye (additional quantities may be approved for the treatment of the second eye when appropriate). Total of 8 kits (1 kit = 7 multi-dose vials) per affected eye per lifetime.
- Age:** 2 years of age or older
- Route of Administration:** Topical eye drop

## PALFORZIA / PEANUT ALLERGEN POWDER-DNFP

**Drug Class:** Allergenic Extracts

**FDA-approved uses:** Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut

**Available dosage forms:** Powder for oral administration supplied in 0.5 mg, 1 mg, 10 mg, 20 mg and 100 mg Capsules or 300 mg Sachets.

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Peanut allergy
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Allergy or Immunology specialist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Documented clinical history of allergy to peanuts or peanut-containing foods
  - A confirmed peanut diagnosis based on one of the following:
    - Peanut skin prick test >8mm
    - Serum IgE to peanut ≥14 kUA/L
    - A reaction that required epinephrine or ED visit
  - Used in conjunction with a peanut-avoidant diet
  - Patient has been prescribed and/or has a refill history of epinephrine auto-injector
  - Prescriber, health care setting, pharmacy, patient must meet manufacturer's REMS requirements
- Age:** 1 year to 17 years of age
  - Patients who start therapy prior to 18 years of age may continue therapy

### **Criteria for continuation of therapy:**

- Positive response to treatment as documented by at least ONE (1) of the following compared to pre-treatment:
  - Reduction in severe allergic reactions
  - Reduction in epinephrine use
  - Reduction in physician/clinic visits due to peanut allergy (physician office/ER visits/hospitalizations)
  - Improvement in quality of life or productivity

**Contraindications/Exclusions/Discontinuation:**

- History of severe or life-threatening episode of anaphylaxis or anaphylactic shock within 60 days
- Uncontrolled asthma
- History of eosinophilic esophagitis (EoE); other eosinophilic gastrointestinal disease; chronic, recurrent, or severe gastroesophageal reflux disease (GERD); symptoms of dysphagia or recurrent gastrointestinal symptoms of undiagnosed etiology
- History of a mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema
- History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension

## PANCREATIC ENZYMES

**Drug Class:** Pancreatic Enzymes

**Preferred Agents:** *Clinical Prior Authorization below*

Creon®  
Zenpep®

**Clinical PA Criteria:**

- Cystic fibrosis or chronic pancreatic insufficiency.

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Pertzye®  
Viokace®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of one preferred agent
- **See additional medication-specific criteria below:**

**PERTZYE®, VIOKACE® (LIPASE/PROTEASE/AMYLASE)**

- Must meet both PDL (trial on preferred medication) and clinical criteria

**Duration of Approval:** 1 year

## PHOSPHATE DEPLETERS

**Drug Class:** Phosphate Depleters

**Preferred Agents:** *Clinical Prior Authorization below*

calcium acetate capsules and tablets  
sevelamer carbonate tablets (generic for Renvela)

**Clinical PA Criteria:**

- Diagnosis of chronic kidney disease

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Auryxia®  
ferric citrate  
Fosrenol® / Fosrenol® powder pak  
lanthanum  
Renvela powder pkts and tablets  
sevelamer carbonate powder pkts (generic for Renvela)  
sevelamer tablets (generic for Renagel)  
Velphoro®  
Xphozah®

**Non-Preferred Agent PA Criteria:**

- Diagnosis of chronic kidney disease; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one month with one preferred medication
- **See additional medication-specific criteria below:**

**VELPHORO®**

- Trial on two preferred medications.

**XPHOZAH®**

- Trial of two preferred medications
- Patient is currently receiving dialysis

**Duration of Approval:** 1 year

## PHOSPHODIESTERASE-4 (PDE-4) INHIBITORS

**Drug Class:** Phosphodiesterase-4 (PDE-4) Inhibitors

**Preferred Agents:** Clinical Prior Authorization below

Roflumilast (generic for Daliresp)

### ROFLUMILAST

- Severe COPD associated with chronic bronchitis and a history of exacerbations; **AND**
- Trial/failure on at least one first-line or second-line agent; **AND**
- Adjunctive therapy (roflumilast must be used in conjunction with first-line or second-line agent)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Daliresp®

### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication
- **See additional medication-specific criteria below:**

### **DALIRESP® (ROFLUMILAST)**

- Severe COPD associated with chronic bronchitis and a history of exacerbations; **AND**
- Trial/failure on at least one first-line or second-line agent; **AND**
- Adjunctive therapy (Daliresp® must be used in conjunction with first-line or second-line agent)

**Duration of Approval:** 1 year

## PLATELET AGGREGATION INHIBITORS

**Drug Class:** Platelet Aggregation Inhibitors

**Preferred Agents:** *No Prior Authorization required*

clopidogrel  
prasugrel  
ticagrelor

**Non-Preferred Agents:** *Prior Authorization Criteria below*

aspirin/dipyridamole  
Brilinta®  
dipyridamole  
Effient®  
Plavix®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- **See additional medication-specific criteria below:**

**EFFIENT® (PRASUGREL)**

- Due to a black box warning related to increase in risk of bleeds in patients > 75
- PDL criteria must be met and the MD will need to document medical necessity or clinical rationale for consideration.

**Duration of Approval:** 1 year

## POTASSIUM BINDERS

**Drug Class:** Potassium Binders

**Preferred Agents:** *No Prior Authorization required*

Lokelma® powder packets  
sodium polystyrene sulfonate oral powder  
SPS Suspension  
kionex suspension

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Veltassa® oral powder packets

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after a one-month trial of one preferred medication

**Duration of Approval:** 1 year

## PRETOMANID® (PRETOMANID)

**Drug Class:** Nitroimidazole Antibiotic

**FDA-approved uses:** Pretomanid is indicated as part of a combination regimen with bedaquiline and linezolid, for the treatment of adults with pulmonary extensively drug resistant (XDR) treatment-intolerant, or nonresponsive multidrug-resistant (NDR) tuberculosis (TB).

**Available dosage forms:** 200mg oral tablets, taken with food.

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Pulmonary extensively drug resistant (XDR) or treatment intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)
- Prescriber Specialty:** Prescribed by or in consultation with an infectious disease specialist or pulmonologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); AND
  - Patient is concomitantly taking bedaquiline (Sirturo) and linezolid (Zyvox) as part of the recommended dosing regimen and use of bedaquiline and linezolid are not contraindicated in patient

**Duration of Approval:** 6 months

## PROGESTATIONAL AGENTS

**Drug Class:** Progestational Agents

**Preferred Agents:**

medroxyprogesterone (oral)  
progesterone (oral)  
norethindrone (oral)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Crinone® (vaginal)  
progesterone (intramuscular)  
Prometrium® (oral)  
Provera® (oral)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of a preferred medication for the indication
- **See additional medication-specific criteria below:**

**CRINONE® (PROGESTERONE VAGINAL)**

- Excluded for diagnosis of fertility

**Duration of Approval:** 1 year

## PROGESTINS FOR CACHEXIA

**Drug Class:** Progestins for Cachexia

**Preferred Agents:** *No Prior Authorization required*

megestrol oral suspension (generic Megace®)

**Non-Preferred Agents:** *Prior Authorization Criteria below*

megestrol oral suspension (generic Megace ES®)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial of one preferred medication

**Duration of Approval:** 1 year

## PROTON PUMP INHIBITORS

**Drug Class:** Proton Pump Inhibitors

**Preferred Agents:** *No Prior Authorization required*

Nexium® susp pkts  
omeprazole (Rx) capsules  
pantoprazole tablets  
Protonix® suspension

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Dexilant® caps  
dexlansoprazole  
esomeprazole magnesium capsules, susp pkts  
esomeprazole magnesium OTC caps, tabs  
Konvomep®  
lansoprazole caps, ODT  
lansoprazole OTC caps  
Nexium® capsules  
omeprazole OTC caps, tabs, ODT  
omeprazole/sodium bicarbonate caps, susp pkts  
pantoprazole suspension  
Prevacid caps, solutabs  
Prilosec® susp  
Protonix® tablets  
Rabeprazole tabs

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication

**Duration of Approval:** 1 year

## PULMONARY ARTERIAL HYPERTENSION (PAH) AGENTS

**Drug Class:** Pulmonary Arterial Hypertension (PAH) Agents

**Preferred Agents:** *Prior Authorization Criteria below*

Adempas®  
Alyq®  
ambrisentan (generic for Letairis)  
Opsumit®  
sildenafil suspension (generic for Revatio)  
sildenafil tablets (generic for Revatio®)  
tadalafil (generic for Adcirca)  
Tracleer® tablets  
Tyvaso®  
Uptravi®  
Ventavis®

**Clinical PA Criteria:**

- Diagnosis of pulmonary hypertension
- Must be prescribed by or in consultation with a cardiologist or pulmonologist

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|   |                                 |
|---|---------------------------------|
| Adcirca®                                | Revatio® <u>suspension</u>      |
| bosentan tablets (generic for Tracleer) | Revatio® tablets                |
| bosentan susp. (generic for Tracleer)   | Tadliq®                         |
| Letairis®                               | Tracleer® suspension            |
| Liqrev®                                 | Tyvaso DPI®                     |
| Opsynvi®                                | Winrevair                       |
| Orenitram ER®                           | Yutrepia® (Treprostinil sodium) |
| Orenitram Titration Kit                 |                                 |

**Non-Preferred Agent PA Criteria:**

- Diagnosis of pulmonary hypertension; **AND**
- Must be prescribed by or in consultation with a cardiologist or pulmonologist; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- See additional medication-specific criteria below

**OPSYNVI® (MACITENTAN/TADALAFIL)**

- Patient is ≥ 18 years of age

- Quantity limit: 1 per day

**TADLIQ® (TADALAFIL)**

- Patient is ≥ 18 years of age

**WINREVAIR® (SOTATERCEPT-CSRK)**

- Patient is ≥ 18 years of age
- Diagnosis of PAH WHO group 1, functional class II or greater; **AND**
- Documented trial and failure of, or contraindication to, at least 2 months of combination therapy including one PDE-5 inhibitor **AND** one ERA; **AND**
- Winrevaair is being used as add on therapy to standard care; **AND**
- Platelet count of > 50,000/mm<sup>3</sup> (>50x10<sup>9</sup>/L), acceptable hemoglobin levels, and other labs in accordance with the product label; **AND**
- Counseling has occurred regarding the need for effective contraception due to risk of embryo-fetal toxicity, and the risk of impaired fertility with use of this medication

**YUTREPIA® (TREPROSTINIL SODIUM)**

- Patient is ≥ 18 years of age; **AND**
- Therapeutic failure with one month trial of preferred trepostinil sodium (e.g., Tyvaso Solution)

**Duration of Approval:** 1 year

## PULMOZYME® / DORNASE ALPHA

**Drug Class:** Mucolytics

**FDA-approved uses:**

- In conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.
- To reduce the risk of respiratory tract infections requiring parenteral antibiotics in CF patients with an FVC  $\geq$  40% of predicted.

**Available dosage forms:** 2.5 mg/2.5 mL in single-use ampules

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** cystic fibrosis
- Duration of Approval:**
  - **Initial Authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Medical records to support a diagnosis of CF
- Prescriber Specialty:**
  - Pulmonologist
  - Infectious disease
- Quantity:** 30 ampules per 30 days
- Age:** at least 5 years of age
- Gender:** male or female
- Route of Administration:** inhalation
- Place of Service:** outpatient

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - FVC
  - Medical records showing stable disease
  - Medical records supporting decreased incidence of respiratory infections

**Contraindications/Exclusions/Discontinuation:**

- Pulmozyme® (dornase alpha) is not authorized for non-FDA-approved indication
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

**Other special considerations:**

- Per FDA-approved label: Pulmozyme<sup>®</sup> (dornase alpha) was studied in patients 3 months to 5 years of age; while clinical trial data are limited in patients <5 years, the use of Pulmozyme<sup>®</sup> (dornase alpha) should be considered for pediatric patients with CF who may experience potential benefit in pulmonary function or who may be at risk of respiratory tract infection.

## QUINOLONES

**Drug Class:** Quinolones

**Preferred Agents:** *No Prior Authorization required*

Cipro® suspension  
ciprofloxacin tablets, suspension  
levofloxacin

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Avelox®  
Baxdela®  
Cipro® tablets  
moxifloxacin  
ofloxacin

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection is caused by an organism that is resistant to the NO PA REQUIRED quinolone medications; **OR**
- Trial/failure (duration = 3 days) of any two preferred quinolone medications; **OR**
- Antibiotic therapy initiated in hospital
- **See additional medication-specific criteria below:**

**MOXIFLOXACIN**

- PDL criteria and quantity limit do not apply when used for the treatment of active drug-susceptible pulmonary tuberculosis for patients  $\geq 12$  years of age.
- Length of approval = 17 weeks when used for the treatment of active drug-susceptible pulmonary tuberculosis

**Quantity Limitations:**

|                               |   |
|-------------------------------|---|
| Cipro® tabs (ciprofloxacin)   | 56 per fill   |
| ciprofloxacin (Cipro®)        | 56 per fill   |
| levofloxacin tabs (Levaquin®) | 250MG - 28 per fill<br>500mg - 28 per fill<br>750mg - 14 per fill |
| moxifloxacin (Avelox®)        | 21 per fill   |

**Duration of Approval:** Date of service; if needed, longer lengths may be approved for transplant recipients

## RANOLAZINE / RANEXA, ASPRUZYO SPRINKLE

**Drug Class:** Antianginal and Anti-ischemic Agents, Non-hemodynamic

**FDA-approved uses:** treatment of chronic angina

**Available dosage forms:**

- Ranolazine 500 mg and 1000 mg extended-release tablets
- Ranexa® 500 mg and 1000 mg extended-release tablets
- Aspruzyo Sprinkle® 500 and 1000 mg extended-release granules

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** chronic stable angina
- Duration of Approval:**
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:** prescribed by, or in conjunction with, a cardiologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):

**Ranolazine ER (RANEXA®)**

- Current progress notes supporting past medication usage, including at least 1 formulary anti-anginal agent from ALL 3 different drug classes:
  - **Beta Blocker:** acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
  - **Calcium Channel Blocker:** amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
  - **Long-Acting Nitrate:** isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
- Labs and medical records supporting indicated diagnosis of chronic angina
- Medical record detailing that Ranexa will be used in addition (add-on) to another anti-anginal medication (i.e., beta-blocker, calcium channel blocker, long-acting nitrate) or patient has contraindications to beta-blockers, calcium channel blockers AND long-acting nitrates

**Aspruzyo Sprinkle® (ranolazine)**

- All the above criteria are met
- Contraindication to ranolazine (Ranexa) ER tablets due to swallowing difficulties **OR**
- Administration via nasogastric (NG) or gastric tube
- Quantity:** 60 tablets or 60 sachets every 30 days (500 mg PO BID initially; may increase to 1,000 mg PO BID)
- Age:** 18 years of age or older
- Route of Administration:**
  - oral - extended-release tablet or granules
  - via NG/gastric tube with extended-release granules (Aspruzyo)

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Current medical records and labs to determine safety and efficacy of treatment

**Contraindications/Exclusions/Discontinuation:**

- Hepatic impairment (Child-Pugh Classes A and B)
- Combined administration with other drugs that are strong inhibitors of CYP3A including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir
- Combined administration with other drugs that are inducers of CYP3A including rifampin, rifabutin, phenobarbital, phenytoin, carbamazepine, and St. John's wort
- Moderate to severe renal impairment CrCl < 60mL/min

**Other special considerations:**

- Not for initial therapy because it can increase QT interval

## SANDOSTATIN® / OCTREOTIDE

**Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).**

**Drug Class:** Somatostatic Agents

**FDA-approved uses:**

- Acromegaly**  
Octreotide Acetate Injection is indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- Carcinoid Tumors**  
Octreotide Acetate Injection is indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
- Vasoactive Intestinal Peptide Tumors (VIPomas)**  
Octreotide Acetate Injection is indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

**Available dosage forms:** Vial 50 mcg/mL, 100 mcg/mL, 200 mcg/mL, 1000 mcg/mL

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Acromegaly
  - Metastatic VIP
  - Chemo/radiation
  - HIV/AIDS-induced diarrhea
  - Metastatic carcinoid tumors
  - Carcinoid tumors
- Duration of Approval:**
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by, or in consultation with, an endocrinologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis confirmed
  - Prescribed by, or in consultation with, an endocrinologist
- Age:** 18 years of age or older
- Route of Administration:** Subcutaneous, intramuscular injection

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - The above criteria has been met
  - Requires decreased or normalized IGF-1 levels

## SENSIPAR® / CINACALCET

**Drug Class:** Calcimimetic, Parathyroid Calcium Receptor Sensitivity Enhancer

**FDA-approved uses:**

- Hyperparathyroidism, primary:** Treatment of severe hypercalcemia in adult patients with primary hyperparathyroidism for who parathyroidectomy would be indicated on the bases of serum calcium levels, but who are unable to undergo parathyroidectomy.
- Hyperparathyroidism, secondary:** Treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis.
- Limitation of use:** Not indicated for use in patients with CKD who are not on dialysis (due to increased risk of hypocalcemia)
- Parathyroid carcinoma:** Treatment of hypercalcemia in adult patients with parathyroid carcinoma.

**Available dosage forms:** Tablet 30 mg, 60 mg, 90 mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** FDA Approved Indication as listed above and above
- Duration of Approval:**
  - **Initial Approval:** 6 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:**  
Nephrologist, Endocrinologist,  
Oncologist or prescriber in  
consultation with specialist.
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **For Secondary hyperparathyroidism due to CKD on dialysis:**
    - Patient is at least 18 years of age, **AND**
    - Trial, failure, or intolerance to an approved formulary phosphate binder trial, **AND**
    - Trial, failure or intolerance to calcitriol or Vitamin D analogs for a minimum of a three-month trial
  - **Labs:**
    - iPTH, calcium, renal function, serum phosphorus. iPTH levels must be > 300 (biPTH >160) and Ca > 8.4 in order to initiate therapy.
  - **For Parathyroid carcinoma (PC):**
    - Patient is at least 18 years of age, **AND**
  - **Labs:**
    - Confirmation the patient has hypercalcemia as defined by baseline serum calcium (Ca) >10mg/dL (corrected for albumin)

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies): continued
  - **For Primary hyperparathyroidism:**
    - Patient is at least 18 years of age, **AND**
    - Confirmation the parathyroidectomy is indicated by patient is unable to undergo parathyroidectomy
  - **Labs:**
    - Severe hypercalcemia as defined by baseline (pre-treatment) serum calcium (Ca) >12 mg/dL (corrected for albumin)

**Criteria for continuation of therapy:**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Absence of unacceptable toxicity from the drug (e.g., hypocalcemia, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease); **AND**
  - **Secondary Hyperparathyroidism (HPT)**
    - Adequate documentation of disease response as indicated by improvement of intact parathyroid hormone (iPTH) levels from baseline; **AND**
    - Current intact parathyroid hormone (iPTH) >150 pg/ml; **AND**
    - Current serum calcium (Ca) >7.5 mg/dL and the patient does not have symptoms of hypocalcemia
  - **Parathyroid Carcinoma (PC)**
    - Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
    - Current serum calcium (Ca) >8.4 mg/dL
  - **Primary Hyperparathyroidism (HPT)**
    - Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
    - Current serum calcium (Ca) >8.4 mg/dL

**Contraindications/Exclusions/Discontinuation:**

- Hypersensitivity to any components of Sensipar
- Hypocalcemia
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## **SIRTURO®/ BEDAQUILINE**

**Drug Class** Antitubercular - Diarylquinoline Antibiotics

**FDA-approved uses:** Multi-drug resistant tuberculosis (MDR-TB)

**Available dosage forms:** Tablets: 20mg, 100mg

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Multi-drug resistant tuberculosis (MDR-TB)
- Duration of approval:**
  - **Initial authorization:** 6 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must be under observed therapy

## SKELETAL MUSCLE RELAXANTS

**Drug Class:** Skeletal Muscle Relaxants

**Preferred Agents:** *No Prior Authorization required (except baclofen solution)*

baclofen tablets  
baclofen oral solution (Ozobax)  
cyclobenzaprine  
methocarbamol 500mg and 750mg tablets  
orphenadrine citrate  
tizanidine tablets

### **BACLOFEN ORAL SOLUTION (OZOBAX)**

- Allow if patient has swallowing difficulties.

**Non-Preferred Agents:** *Prior Authorization Criteria below*

|  |                                |
|--|--------------------------------|
| Amrix®                                 | Lyvispah®                      |
| baclofen suspension (generic Fleqsuvy) | metaxalone                     |
| cyclobenzaprine ER                     | methocarbamol 1000mg tablet    |
| chlorzoxazone                          | Norgesic Forte®                |
| Dantrium®                              | orphenadrine-aspirin-caffeine  |
| dantrolene sodium                      | Tanlor®                        |
| Fexmid®                                | Tonmya®                        |
| Fleqsuvy®                              | tizanidine capsules            |
| Lorzone®                               | Zanaflex® capsules and tablets |

### **Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with two preferred medications
- Non-preferred criteria do not apply to dantrolene if diagnosis is cerebral palsy
- **See additional medication-specific criteria below**

### **FLEQSUVY ORAL SOLUTION (BACLOFEN) (PDL criteria do not apply)**

- Trial and failure with preferred oral solution

### **LYVISPAH GRANULE PACKETS (BACLOFEN) (PDL criteria do not apply)**

- Trial and failure with preferred oral solution

### **METHOCARBAMOL 1000MG TABLET**

- **Bypass PDL criteria except require trial and failure of both PDL preferred methocarbamol 500mg and 750mg tablets**

**TONMYA (CYCLOBENZAPRINE HCL)**

- Patient is 18 years of age or older; **AND**
- Diagnosis of fibromyalgia; **AND**
- Prescriber will reduce the dose for patients age 65 years or older to 1 tablet per day
- Quantity Limit: 2 tablets per day

**Duration of Approval: 1 year**

## SODIUM PHENYL BUTYRATE AND TAURURSODIOL

**Drug Class:** ALS Agent- Histone deacetylase inhibitor

**FDA-approved uses** treatment of amyotrophic lateral sclerosis (ALS)

**Available dosage forms:** Sodium phenylbutyrate 3g/ taurursodiol 1 g packet

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** ALS
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Prescriber Specialty:** Prescribed by or in consultation with a neurologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of ALS as determined by revised El Escorial criteria
  - Initiation of drug is within 18 months of symptom onset
  - Slow vital capacity (SVC) exceeding 60% of the predicted
  - Current use or has failed previous treatment with riluzole
- Age:** ≥ 18 years old
- QL:** 60 packets per 30 days

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider attestation of positive clinical response
  - Medication is prescribed at an FDA approved dose

## SORIATANE® / ACITRETIN

**Drug Class:** Dermatological - Antipsoriatic Agents Systemic, Vitamin A Derivatives

**FDA-approved uses:** Severe Psoriasis

**Available dosage forms:** Capsules 10 mg, 17.5 mg, 25 mg

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Moderate to Severe Psoriasis
- Duration of Approval:**
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 1 year
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - 90 day trial of methotrexate **AND**
  - 90 day trial of high dose topical steroid (e.g. betamethasone augmented, clobetasol, halobetasol)
- Prescriber Specialty:** Dermatology
- Quantity:** Max 2 capsules per day
- Route of Administration:** Oral

### **Criteria for continuation of therapy**

- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Requires a positive response to therapy

### **Contraindications/Exclusions/Discontinuation:**

- Soriatane must not be used by females who are pregnant, or who intend to become pregnant during therapy or at any time for at least 3 years following discontinuation of therapy.
- Soriatane is contraindicated in patients with impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

### **Other special considerations:**

- Pregnancy Category X.
- Soriatane should not be taken with methotrexate or tetracyclines.
- Soriatane should not be used in patients with known alcohol abuse.

## SYNAGIS® / PALIVIZUMAB

**Administration Disclaimer: The following criteria set is for the retail pharmacy benefit. This criteria set DOES NOT apply for administration as a medical benefit (“buy and bill”).**

**Drug Class:** Immunological Agent/Monoclonal Antibody

**FDA-approved uses:** Prevention of RSV for children <2yo at high risk of RSV disease  
Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis®) **may be considered medically necessary** in the following infants and children **to a maximum of five monthly doses per RSV season:**

- Prematurity:**
  - Infants who are younger than 12 months of age at the start of RSV season and are born before **29 weeks 0 days** gestation.
- Chronic Lung Disease (CLD):**
  - Preterm infants younger than 12 months of age who develop CLD of prematurity (defined as gestational age <32 weeks, 0 days) and required >21% oxygen for at least the first 28 days after birth.
  - Infants between 12 and 24 months of age who developed CLD of prematurity as defined above and who continue to require medical support (chronic corticosteroid therapy, diuretic therapy, supplemental oxygen or bronchodilator therapy) within 6 months of the start of RSV season.
- Heart Disease:**
  - Infants who are 12 months of age or younger with hemodynamically significant Congenital Heart Disease (CHD). Those children with CHD who are most likely to benefit from immunoprophylaxis include those with:
    - acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures ; **or**
    - moderate to severe pulmonary hypertension; **or**
    - cyanotic heart disease (if recommended by a pediatric cardiologist).
  - Additionally, children younger than 24 months who undergo cardiac transplantation during the RSV season may be considered for prophylaxis.
- Immune prophylaxis for RSV **is considered not medically necessary** for
  - Infants and children with hemodynamically insignificant heart disease including but not limited to:
    - secundum atrial septal defect,
    - small ventricular septal defect,
    - pulmonic stenosis,
    - uncomplicated aortic stenosis,
    - mild coarctation of the aorta,
    - patent ductus arteriosus
    - Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure.
    - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

**Note:** Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-corporeal membrane oxygenation for infants and children younger than 24 months.

- Neuromuscular disease, congenital airway anomaly or pulmonary abnormality**
  - Infants under 12 months of age with neuromuscular disease, congenital anomalies of the airway or pulmonary abnormalities that impair the ability to clear secretions from the upper airway because of ineffective cough.
- Immunocompromised**
  - Infants and children, who are 24 months of age or younger, who are profoundly immunocompromised because of chemotherapy or other conditions during the RSV season.

**Available dosage forms:** Solution: 50 mg/0.5 ml vial, 100 mg/ml vial for IM injection

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Medically necessary FDA-approved uses as listed above
- Duration of Approval**
  - **Initial Approval:** Maximum of 5 doses per RSV season. Typically RSV season is October 1- May 1. This must be confirmed on an annual basis.
  - **Continuation of Therapy:** Considered in a case by case basis by each plan. If any infant or young child receiving monthly Synagis prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Children who have *not* had a dose of Beyfortus™ (nirsevimab) in the current RSV season; **AND**
  - Mother did not receive vaccination against RSV in the 2<sup>nd</sup> or 3<sup>rd</sup> trimester; **AND**
  - Infants who are younger than 12 months of age at the start of the Synagis season and who are born before 29 weeks, 0 days' gestation.
  - Infants in the first 12 months of life, who are diagnosed with CLD (chronic lung disease) of prematurity defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
  - Infants in the second year of life who are diagnosed with CLD (as per above criteria) **AND** who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) within the 6-month period before the start of the second RSV season.
  - Children who are 12 months or younger with hemodynamically significant CHD as evidenced by:
    - acyanotic heart disease and are receiving medication to control congestive heart failure, and will require cardiac surgical procedures

- ❑ **Documentation Requirements continued** (e.g. Labs, Medical Record, Special Studies):
  - Infants with moderate to severe pulmonary hypertension. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
  - Child younger than 24 months who will be profoundly immunocompromised during the RSV season.
- ❑ **Quantity:**
  - The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children. For qualifying infants up to 5 doses per RSV season must be allowed. Qualifying infants born during the RSV season may require fewer doses.
- ❑ **Age:** 24 months and younger, See criteria for authorization for age specific indications.
- ❑ **Route of Administration:** Intramuscular

**Criteria for continuation of therapy:**

- ❑ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Requests for coverage outside of RSV season will require authorization.

**Contraindications/Exclusions/Discontinuation:**

- History of severe prior reaction to palivizumab or any component of the formulation.
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

**Other special considerations:**

- Routine use in cystic fibrosis and Down Syndrome is not recommended.
- The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer.

**References**

The American Academy has issued updated guidance for the 2021-2022 season.

[Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2021-2022 RSV Season \(aap.org\)](#)

To see RSV virology trends by state/region, please click the link below:

<https://www.cdc.gov/surveillance/nrevss/rsv/state.html>

# TAZAROTENE

**Drug Class:** Dermatological - Antipsoriatic Agents Topical

**FDA-approved uses:**

- Indicated for the topical treatment of plaque psoriasis and acne vulgaris

**Available dosage forms:**

**Formulary:**

- Tazarotene Cream, 0.05% and 0.1%
- Tazarotene Gel, 0.05% and 0.1%

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Psoriasis or acne vulgaris
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** for up to 12 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Prescribed to treat an FDA approved indication for Tazarotene **AND**
  - Diagnosis specific requirements:
    - For the treatment of psoriasis
      - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid
      - **OR**
      - Documented trial, failure, or intolerance of one low or medium potency topical steroid and justification for avoidance of a higher potency topical steroid **OR**
      - Topical steroid avoidance due to pediatric age **AND**
      - Documented trial, failure or intolerance to a topical vitamin D analogue (i.e. calcipotriene or calcitriol) or a clinical reason why both cannot be used.
    - For the treatment of acne vulgaris
      - Documented trial, failure or intolerance to one of the following:
        - Topical adapalene
        - Topical tretinoin
- Quantity:** Appropriate amount to cover affected area for up to 34 days based on provider estimate or body surface area (BSA) estimate.
  - Prescribing information recommends a “thin layer” defined as 2 mg/cm<sup>2</sup> for approved diagnoses.
- Age:**
  - Treatment of acne vulgaris: patients ≥ 12 years old
  - Treatment of psoriasis:
    - Cream – patients ≥ 18 years old
    - Gel – patients ≥ 12 years old

- Route of Administration:** Topical

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Attestation that tazarotene has contributed to a positive response or patient is stable on therapy.

**Contraindications/Exclusions/Discontinuation:**

- Warning of embryofetal toxicity:
  - Use of topical retinoids should be avoided during pregnancy.
    - Females of child-bearing potential should have a negative pregnancy test within 2 weeks prior to initiating treatment and use an effective method of contraception during treatment.
    - If member is pregnant, Tazarotene is contraindicated and alternate therapy should be utilized.
- For the treatment of psoriasis in children, using the gel form, it is recommended to limit application to  $\leq 20\%$  of BSA.

## TOPICAL ANTIBIOTICS

**Drug Class:** Topical Antibiotics

**Preferred Agents:** *No Prior Authorization required*

mupiricin ointment

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Centany®  
mupiricin cream  
Xepi® Cream

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Therapeutic failure after one month with one preferred medication
- **See additional medication-specific criteria below:**

**XEPI® CREAM (OZENOXACIN)**

- Quantity Limit = 2 tubes per month
- Length of authorization – 1 month

**Duration of Approval:** 1 year

## TOPICAL STEROIDS – LOW POTENCY

**Drug Class:** Topical Steroids – Low Potency

**Preferred Agents:** *No Prior Authorization required*

hydrocortisone acetate cream  
hydrocortisone acetate ointment  
hydrocortisone/aloe  
hydrocortisone cream  
hydrocortisone lotion  
hydrocortisone ointment

**Non-Preferred Agents:** *Prior Authorization Criteria below*

aclometasone dipropionate ointment and cream  
Capex<sup>®</sup> Shampoo  
Derma-smooth – FS<sup>®</sup>  
Desonide<sup>®</sup> ointment, cream, lotion  
fluocinolone 0.01% oil  
hydrocortisone solution  
Texacort<sup>®</sup>

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects
- Trial and failure of 14 days with **one** of the preferred medications

**Duration of Approval:** For the duration of the prescription up to 6 months

## TOPICAL STEROIDS – MEDIUM POTENCY

**Drug Class:** Topical Steroids – Medium Potency

**Preferred Agents:** *No Prior Authorization required*

fluocinolone acetonide solution  
fluticasone propionate cream  
fluticasone propionate ointment  
mometasone furoate ointment  
mometasone furoate cream  
mometasone furoate solution

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Beser Kit  
Beser Lotion  
betamethasone valerate foam  
clocortolone cream  
fluocinolone acetonide cream  
flurandrenolide lotion, ointment  
fluticasone propionate lotion  
hydrocortisone butyrate cream, lotion, ointment, solution  
hydrocortisone valerate cream and ointment  
Pandel®  
Synalar® solution, cream and ointment  
Synalar TS® kit

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects
- Trial and failure of 14 days with **one** of the preferred medications

**Duration of Approval:** For the duration of the prescription up to 6 months

## TOPICAL STEROIDS – HIGH POTENCY

**Drug Class:** Topical Steroids – High Potency

**Preferred Agents:** *No Prior Authorization required*

betamethasone dipropionate cream, lotion, ointment  
betamethasone valerate cream, lotion, ointment  
fluocinonide cream, ointment, gel and solution  
triamcinolone acetonide cream, lotion, ointment

**Non-Preferred Agents:** *Prior Authorization Criteria below*

amcinonide cream  
betamethasone dipropionate augmented cream, gel  
betamethasone dipropionate augmented lotion, ointment  
clobetasol 0.025% cream  
desoximetasone cream, ointment, gel, and spray  
diflorasone diacetate cream and ointment  
Diprolene® ointment  
fluocinonide emollient  
halcinonide  
Halog® cream, ointment, solution  
Kenalog® aerosol  
Topicort® cream, ointment, gel and spray  
triamcinolone spray

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects
- Trial and failure of 14 days with **one** of the preferred medications

**Duration of Approval:** For the duration of the prescription up to 6 months

## TOPICAL STEROIDS – VERY HIGH POTENCY

**Drug Class:** Topical Steroids – Very High Potency

**Preferred Agents:** *No Prior Authorization required*

clobetasol propionate solution  
clobetasol propionate 0.05% cream  
clobetasol propionate ointment  
halobetasol propionate cream  
halobetasol propionate ointment

**Non-Preferred Agents:** *Prior Authorization Criteria below*

ApexiCon® E Cream  
clobetasol emollient and lotion  
clobetasol propionate foam, gel, spray and shampoo  
Clobex® spray and shampoo  
Clodan® shampoo and kit  
halobetasol propionate (generic for Lexette®)  
halobetasol prop lotion (generic for Ultravate)  
Olux®  
Tovet Kit  
Tovet Emollient  
Ultravate® lotion

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects
- Trial and failure of 14 days with **one** of the preferred medications

**Duration of Approval:** For the duration of the prescription up to 6 months

## TRYVIO / APROCITENTAN

**Drug Class:** Endothelin Receptor Antagonist (ERA)

**FDA-approved uses:** Resistant Hypertension (RH)

**Available dosage forms:** 12.5 mg tablet

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Resistant Hypertension despite concurrent use of 3 or more antihypertensive drug classes
- Duration of approval:**
  - **Initial authorization:** 1 year
  - **Continuation of Therapy:** 1 year
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation demonstrating failure to reach blood pressure goal despite concurrent use of 3 or more antihypertensive drug classes; **AND**
  - Clinical documentation demonstrating failure to reach blood pressure goal despite addition of a mineralocorticoid receptor antagonist (i.e., spironolactone OR eplerenone) to the current 3 drug regimen; **OR**
  - Contraindication (i.e. hyperkalemia, renal impairment, etc.) or drug to drug interaction (i.e. CYP3A4 Inhibitors, potassium-sparing diuretics, etc.) preventing the use of both spironolactone and eplerenone; **AND**
  - For patients who can become pregnant, the prescriber attests:
    - patient is not pregnant or lactating
    - patient has been counseled on the risk of major birth defects AND to use acceptable methods of contraception before treatment with TRYVIO, during treatment with TRYVIO, and for one month after treatment discontinuation;
- Specialty:** Prescribed by or in consultation with a specialist with experience in the treatment of RH such as a cardiologist, nephrologist or endocrinologist
- Quantity:** 1 tablet per day
- Age:** 18 years of age and older

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - For patients who can become pregnant, prescriber attests patient is not pregnant or lactating
  - Clinical documentation demonstrates blood pressure improvement compared to baseline
  - Prescriber attests that patient has not experienced unacceptable adverse effects from TRYVIO therapy (i.e. hepatotoxicity, clinically significant anemia, clinically significant edema)

### **Contraindications/Exclusions/Discontinuation:**

Pregnancy/lactation

## ULCERATIVE COLITIS – ORAL

**Drug Class:** Ulcerative Colitis – Oral

**Preferred Agents:** *No Prior Authorization required*

mesalamine (generic for Lialda)  
Pentasa®  
sulfasalazine/ sulfasalazine DR

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Azulfidine DR®  
Balsalazide  
budesonide ER (generic for Uceris)  
Delzicol®  
Dipentum®  
Giazo®  
Lialda®  
mesalamine (generic for Apriso)  
mesalamine (generic for Asacol)  
mesalamine (generic for Delzicol)  
mesalamine (generic for Pentasa)

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure after one-month trial with one preferred medication

**Duration of Approval:** 1 year

## URINARY TRACT ANTISPASMODICS

**Drug Class:** Urinary Tract Antispasmodics

**Preferred Agents:** *No Prior Authorization required*

fesoterodine ER  
Myrbetriq®  
oxybutynin / oxybutynin ER  
solifenacin  
tolterodine/ tolterodine ER  
trospium

**Non-Preferred Agents:** *Prior Authorization Criteria below*

darifenacin ER  
Detrol®/ Detrol LA®  
Ditropan XL®  
flavoxate HCL  
Gemtesa®  
mirabegron ER  
Oxytrol®  
Toviaz®  
trospium ER  
Vesicare®  
Vesicare LS Suspension®

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial of one preferred medication

**Duration of Approval:** 1 year

## UTERINE DISORDER TREATMENTS

**Drug Class:** Uterine Disorder Treatments

**Preferred Agents:** *Clinical Prior Authorization below*

Myfembree®  
OriaHnn®  
Orilissa®

### **ORIAHNN® (ELAGOLIX/ESTRADIOL/NORETHINDRONE)**

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
- Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Quantity limit: 56 tablets per 28 days

### **ORILISSA® (ELAGOLIX) 150MG**

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis; **AND**
- Failure on an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Quantity limit: 28 tablets per 28 days

### **ORILISSA® (ELAGOLIX) 200MG**

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis with dyspareunia; **AND**
- Failure on an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Treatment duration of Orilissa 200mg twice daily has not exceeded a total of 6 months; **AND**
- Quantity limit: 56 tablets per 28 days

### **MYFEMBREE® (RELUGOLIX/NORETHINDRONE)**

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of
  - Uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
  - Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **OR**
  - Moderate to severe pain associated with endometriosis; **AND**
  - Failure on an adequate trial of the following therapies:
    - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
    - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C); **AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Quantity limit: 28 tablets per 28 days

### **□ Duration of Approval:**

- Oriahnn, Orilissa 150mg and Myfembree = 1 year (maximum total duration of 24 months)
- Orilissa 200mg = 6 months (maximum duration)

## VAGINAL ANTIBIOTICS

**Drug Class:** Vaginal Antibiotics

**Preferred Agents:** *No Prior Authorization required*

Cleocin (clindamycin) Ovules  
Clindamycin (generic for Cleocin) 2% cream  
Clindesse (clindamycin) 2% Cream  
metronidazole (generic for Metro-Gel and Vandazole) 0.75% gel  
Nuessa (metronidazole) 1.3% Gel

**Non-Preferred Agents:** *Prior Authorization Criteria below*

Cleocin (clindamycin) 2% Cream  
metronidazole 1.3% Gel  
Vandazole (metronidazole) 0.75% Gel  
Xaciato (clindamycin) 2% Gel

**Non-Preferred Agent PA Criteria:**

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one preferred medication
- **See additional medication-specific criteria below:**

**XACIATO® (CLINDAMYCIN)**

- Patient age is 12 years or older

**Duration of Approval:** 6 months

## VEMLIDY / TENOFOVIR ALAFENAMIDE

**Drug Class:** Anti-Retroviral – Nucleotide Reverse Transcriptase Inhibitor

**FDA-approved uses:** Treatment of Chronic Hepatitis B Infection

**Available dosage forms:** Tablet 25 mg

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Chronic Hepatitis B Infection
- Duration of approval:**
  - a. **Initial authorization:** 6 months
  - b. **Continuation of Therapy:** 12 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - a. Diagnosis of Chronic Hepatitis B infection with compensated liver disease; **AND**
  - b. Trial, failure, or contraindication to Entecavir; **AND**
  - c. Trial of tenofovir disoproxil fumarate unless one of the following conditions are met:
    - i. History of osteoporosis or osteopenia
    - ii. Renal impairment defined by creatinine clearance (CrCl) < 50 mL/min or history of chronic renal disease.
    - iii. Trial of tenofovir disoproxil fumarate is inappropriate; **OR**
  - d. Persistent viremia or breakthrough infection while taking lamivudine **or** adefovir [*NOTE: lamivudine and adefovir are no longer recommended in current guidelines*]; **AND**
  - e. Attestation: Confirmation of no HIV risk or negative HIV status
- Quantity:** 30 tablets per 30 days
- Age:** 6 and older

### **Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - a. Confirmation of positive clinical response.
  - b. Confirmation of continued monitoring according to available guidelines (i.e. HBV DNA, ALT, etc.)
  - c. CrCl remains  $\geq 15$  mL/min

**Contraindications/Exclusions/Discontinuation:**

1. HIV and HBV coinfection: Should not be used as a single agent for the treatment of HIV due to resistance development risk
2. If HIV positive - provide further justification
3. For females: There have been no data reported to the antiretroviral registry related to the use of this drug in pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines note data are insufficient to recommend tenofovir alafenamide for initial therapy in antiretroviral-naive pregnant women. Tenofovir disoproxil fumarate (Viread) preferred in pregnant women.
4. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

# VERQUVO / VERICIGUAT

**Drug Class** : soluble guanylate cyclase (sGC) stimulator

**FDA-approved uses:** To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

**Available dosage forms:** 2.5 mg, 5 mg, 10 mg tablets

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Symptomatic chronic heart failure with ejection fraction less than 45%
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:** Cardiology, or prescribed in consult with cardiology
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Documentation that member has chronic heart failure, New York Heart Association [NYHA] Class II-IV who has had a decompensation while on standard therapy for heart failure
  - Documentation of a left ventricular ejection fraction (LVEF) of less than 45%
  - Documentation that member is currently taking or has a contraindication to ALL of the following:
    - ACE inhibitor or ARB or Entresto
    - Beta blocker
    - Oral diuretic (not applicable if member had IV diuretics in previous 3 months)
  - History of hospitalization for heart failure in the previous 6 months or required outpatient IV diuretics for heart failure in the previous 3 months.
  - For female patients of childbearing potential: Documentation of a negative pregnancy test in the previous 30 days and provider attestation that member has been counseled on the risks and advised to use contraception throughout treatment with and one month following Verquvo administration.
  - Prescriber attestation that member is not or will not be using VERQUVO concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or PDE-5 inhibitors (e.g. sildenafil, tadalafil, vardenafil and avanafil).
  
- Quantity:** maintenance dosing, 30 tablets per 30 days
- Age:** 18 years or older
- Route of Administration:** Oral

**Criteria for continuation of therapy:**

- Documentation that member has had no intolerable adverse effects from treatment
- Documentation that member is responding positively to treatment demonstrated by improvement or slowing of decline in signs and symptoms of heart failure.

**Contraindications/Exclusions/Discontinuation:**

VERQUVO is contraindicated in patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators. VERQUVO is contraindicated in pregnancy.

**Other special considerations:**

Obtain a pregnancy test in females of reproductive potential prior to initiating treatment with VERQUVO in females of reproductive potential. Based on data from animal reproduction studies, VERQUVO may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with VERQUVO and for at least one month after the final dose.

Concomitant use of VERQUVO with PDE-5 inhibitors is not recommended because of the potential for hypotension.

## VOQUEZNA (VONOPRAZAN)

**Drug Class:** potassium-competitive acid blocker

**FDA-approved uses:**

- healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- relief of heartburn associated with non-erosive Gastroesophageal reflux disease (GERD) in adults
- in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults – ***if the request is for treatment of H. pylori, please refer to the MHP Common Formulary Prior Authorization Criteria for H. Pylori Treatment; Non-preferred agents section***
- *in combination* with amoxicillin for the treatment of H. pylori infection in adults – ***if the request is for treatment of H. pylori, please refer to the MHP Common Formulary Prior Authorization Criteria for H. Pylori Treatment; Non-preferred agents section***

**Available dosage forms:**

Oral Tablet: 10 MG, 20 MG

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Erosive esophagitis; non-erosive gastroesophageal reflux disease (GERD); treatment of H. pylori infection\* (*to review Voquezna requests to treat H. pylori, refer to MHP Common Formulary Prior Authorization Criteria for H. pylori treatment for Coverage Criteria/Limitations*)
- Duration of approval:**
  - **Initial authorization:** 8 months
  - **Continuation of Therapy:** 6 months
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of erosive esophagitis; **OR**
  - Diagnosis of non-erosive gastroesophageal reflux disease (GERD); **AND**
  - Clinical documentation demonstrates patient had a therapeutic failure after one-month trial with one preferred proton pump inhibitor (PPI)
- Quantity:** 1 tablet per day
- Age:** 18 years of age and older

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation demonstrates significant improvement in signs and symptoms of erosive esophagitis or non-erosive gastroesophageal reflux disease (GERD)
  - Provider attests that continuation beyond the FDA-approved duration of therapy is medically necessary
  - Provider attests risks vs. benefits of continuation have been weighed and discussed with the patient (i.e. Risks of C. difficile-associated infection, fractures, fundic gland polyps, hypomagnesemia, tubulointerstitial nephritis, vitamin B12 deficiency, etc.)

## VTAMA / TAPINAROF

**Drug Class:** Dermatological - Antipsoriatic Agents Topical

**FDA-approved uses:**

- An aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults and atopic dermatitis indications 2 years of age or older.

**Available dosage forms:**

- Cream, 1% (10mg/gram)

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Plaque psoriasis, Atopic dermatitis
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** for up to 12 months
- Prescriber Specialty:** Prescribed by, or in consultation with, a dermatologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **Plaque Psoriasis:**
    - Prescribed to treat plaque psoriasis; **AND**
    - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid; **AND**
    - Documented trial, failure, or intolerance to topical calcipotriene, calcitriol, tazarotene, or combination products containing prior stated ingredients; **OR**
    - Clinical documentation as to why therapies listed above are not appropriate; **AND**
    - For quantities greater than 60 grams per 30 days, prescriber must attest that the volume of drug is necessary for adequate treatment of the patient
  - **Atopic Dermatitis:**
    - Prescribed to treat atopic dermatitis; **AND**
    - Documented trial, failure, or intolerance to at least one topical steroid; **OR**
    - Clinical documentation as to why topical steroid therapy is not appropriate; **AND**
    - For quantities greater than 60 grams per 30 days, prescriber must attest that the volume of drug is necessary for adequate treatment of the patient
- Quantity:** 1 tube (60 grams) per 30 days
- Age:** For Plaque psoriasis: ≥ 18 years old; For Atopic dermatitis ≥ 2 years old

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Attestation that topical tapinarof has contributed to a positive response or patient is stable on therapy.

## YORVIPATH/ PALOPEGTERIPARATIDE

**Drug Class:** Parathyroid Hormone Analog

**FDA-approved uses:** Treatment of hypoparathyroidism in adults.

**Available dosage forms:** 168 mcg/0.56 mL pen, 294 mcg/0.98 mL pen, 420 mcg/1.4 mL pen

### **Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:** Hypoparathyroidism
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** 12 months
- Prescriber Specialty:** Endocrinologist or in consultation with an endocrinologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone.
  - Current labs (within 60 days of request) have been submitted for the following:
    - Albumin-corrected serum calcium (must be > 7.8mg/dL to start therapy)
    - Serum vitamin D level (must be greater than or equal to 20 ng/mL to start therapy)
- Medication is prescribed at an FDA approved dose (maximum dose of 30mcg once daily).
- Quantity:** 2 pens per 28 days
- Age:** 18 years of age or older
- Route of Administration:** subcutaneous

### **Criteria for continuation of therapy:**

- Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL)
- ONE** of the following:
  - Patient no longer requires active vitamin D or therapeutic doses of elemental calcium greater than 600 mg per day, **OR**
  - Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of elemental calcium and is still actively titrating doses of Yorvipath
- Medication is prescribed at an FDA approved dose

## ZORYVE / ROFLUMILAST

**Drug Class:** Dermatological - Antipsoriatic Agents Topical

**FDA-approved uses:**

- Zoryve 0.05% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age
- Zoryve 0.15% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for mild to moderate atopic dermatitis in adults and pediatric patients 6 years and older.
- Zoryve 0.3% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
- Zoryve Foam - A phosphodiesterase 4 (PDE-4) inhibitor indicated for seborrheic dermatitis in patients 9 years of age and older.

**Available dosage forms:**

- Cream, 0.05% (0.5mg/gram)
- Cream, 0.15% (1.5mg/gram)
- Cream, 0.3% (3mg/gram)
- Foam, 0.3% (3mg/gram)

**Coverage Criteria/Limitations for initial authorization:**

- Diagnoses:**
  - Plaque psoriasis (Zoryve 0.3% Cream)
  - Mild to moderate atopic dermatitis (Zoryve 0.15% Cream, Zoryve 0.05% Cream)
  - Seborrheic dermatitis (Zoryve Foam)
- Duration of approval:**
  - **Initial authorization:** 6 months
  - **Continuation of Therapy:** for up to 12 months
- Prescriber Specialty:** Prescribed by, or in consultation with, a dermatologist
- Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **All requests**
    - Prescribed to treat an FDA approved indication for topical Roflumilast **AND**
    - Prescribed volume is appropriate for treating the estimated body surface area affected or prescriber attests that the volume is necessary for up to a 34-day supply per fill. **AND**
    - Additional diagnosis-specific criteria below:
  - **For Plaque psoriasis**
    - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid **AND**
    - Documented trial, failure, or intolerance to topical calcipotriene, calcitriol, tazarotene, or combination products containing prior stated ingredients **OR**
    - Clinical documentation as to why therapies listed above are not appropriate
  - **For Seborrheic dermatitis**
    - Documented trial, failure, or intolerance to at least one topical steroid **AND**
    - Documented trial, failure, or intolerance to at least one topical antifungal **OR**

- Clinical documentation as to why prerequisite therapies listed above are not appropriate.
- **For Mild to moderate atopic dermatitis**
  - Documented trial, failure, or intolerance to at least one topical steroid; **OR**
  - Clinical documentation as to why prerequisite therapies listed above are not appropriate.
- Quantity:** See criteria
- Age:**
  - 0.05% Cream ≥ 2 years old
  - 0.15% & 0.3% Cream ≥ 6 years old
  - Foam ≥ 9 years old
- Route of Administration:** Topical

**Criteria for continuation of therapy:**

- Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Attestation that topical roflumilast has contributed to a positive response or patient is stable on therapy.