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## ACE INHIBITORS

**Drug Class**: ACE Inhibitors

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

benazepril/ benazepril HCT
enalapril/ enalapril HCT
lisinopril/ lisinopril HCT

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

Accupril®
Accuretic®
Altace®
captopril/ captopril HCT
enalapril solution (generic Epaned)
Epaned®
fosinopril/ fosinopril HCT
Lotensin®/ Lotensin HCT®
moexipril / moexipril HCT
Monopril® / Monopril HCT®
perindopril
Prinivil®
Qbrelis®
quinapril / quinapril HCT
ramipril
trandolapril
Vasotec® / Vaseretic®
Zestril® / Zestoretic®

**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 on one preferred medication
- **See additional medication-specific criteria below:**

**EPANED® *(ENALAPRIL SOLUTION)***

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

**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*

Catapres TTS®
clonidine
clonidine ER
clonidine transdermal
guanfacine
methyldopa

**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®
Razadyne ER®
rivastigmine patch

**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.

## 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*

Androderm®
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:** *No Prior Authorization required*

Entresto®

**Quantity Limit:** 60 tablets per 30 days

## ANGIOTENSIN RECEPTOR ANTAGONISTS

**Drug Class**: Angiotensin Receptor Antagonists

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

losartan/ losartan HCT
Olmesartan/ olmesartan HCT
valsartan/ valsartan HCT

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

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

**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 on one preferred medication

❒ **Duration of Approval**: 1 year

## ANTIBIOTICS – INHALED

**Drug Class**: Antibiotics – Inhaled

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

Bethkis® ampule
Cayston® inhalation solution
Kitabis® pak
Tobi-Podhaler®

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

TOBI inhalation solution
tobramycin solution (Generic for 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
- 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

❒ **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*

Lonhala Magnair nebulizer solution
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

## ANTICOAGULANTS

**Drug Class**: Anticoagulants

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

Eliquis®
enoxaparin
Jantoven®
Pradaxa®
warfarin
Xarelto®/ Xarelto® Dose Pack

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

Arixtra®
Coumadin®
dabigatran etexilate
fondaparinux
Fragmin® syringes and vials
Lovenox®
Savaysa®

**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 on one preferred medication
- **See additional medication-specific criteria below:**

**SAVAYSA®**

- Trial on Xarelto®; **AND**
- Patient must be 18 years or older

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

## ANTIEMETICS

**Drug Class**: Antiemetics

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

Emend® 80mg
granisetron
ondansetron

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

Akynzeo®
Aprepitant
Emend Pack®
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 | 15 per fill |
| granisetron (Kytril®) 1mg/5ml oral soln | 150 mL per fill |
| ondansetron (Zofran®) | 4mg, 8mg tab – 15 per fill<br>24mg tab – 10 per fill<br>ODT – 15 per fill<br>4mg/5ml oral solution - 75mL per fill |
| Sancuso® (granisetron) transdermal patch | 1 patch every 5 days |
| rolapitant (Varubi®) | 2 tablets per 7 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*

Ancobon®
Brexafemme®
Cresemba®
Diflucan®
flucytosine
griseofulvin tablet
griseofulvin microsize tablets
griseofulvin ultramicrosize tab
itraconazole
Noxafil®
Noxafil DR®
Noxafil PowderMix Suspension
Oravig®
posaconazole
Sporanox®
Tolsura®
Vfend®
Vivjoa®
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 ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period; **AND**
- Patient is a post-menarchal female
- Quantity Limit: Treatment = 4 tablets, Maintenance = 24 tablets
- Length of approval: Treatment = one time, Maintenance = 6 months

**CRESEMBA®**

- Diagnosis of aspergillosis; **AND**
- Patient is 18 years or older; **AND**
- Trial on voriconazole/Vfend or amphotericin B - approve without trials if intolerant to prerequisite meds or renal dysfunction

**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 |
| Diflucan® 150 mg tab *(fluconazole)* | 2 per fill |
| fluconazole 150 mg tabs *(Diflucan®)* | 2 per fill |
| *terbinafine (*Lamisil®*)* | 84 per fill |
| Sporanox® *(itraconazole) – brand & generic* | 100 mg – 84 per fill<br>250 mg kit – 34 per fill<br>Solution – 840 per fill |
| terbinafine tabs *(Lamisil®)* | 84 per fill |
| Vivjoa® *(oteseconazole)* | 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
ketoconazole
miconazole nitrate
nystatin
nystatin/triamcinolone cream, ointment
tolnaftate cream, powder

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

butenafine
Ciclodan®
ciclopirox suspension (generic for Loprox®)
ciclopirox gel, shampoo, kit
clotrimazole / betamethasone lotion
econazole nitrate cream
Ertaczo® cream
Exelderm® cream, solution
Extina® foam
Fungoid-D®
Jublia ® solution
Kerydin® solution
ketoconazole foam
Ketodan® foam
Loprox® shampoo, susp, cream
Lotrimin AF® cream
luliconazole cream
Luzu® cream
Mentax® cream
miconazole/zinc oxide/petrolatum
Naftin® gel, cream
naftifine cream gel
Oxistat® cream, lotion
tavaborole solution
Vusion® ointment

**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:**

**JUBLIA® *(EFINACONAZOLE)***

- Diagnosis of toenail onychomycosis; and patient age 18 years or older; and trial and failure on ciclopirox or allergy to ciclopirox

**KERYDIN® *(TAVABOROLE)***

- Diagnosis of toenail onychomycosis; and patient must be 18 years or older; and documented trial and failure on ciclopirox or allergy to ciclopirox (applies to brand and generic)

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

## ANTIHISTAMINES – 2ND GENERATION

**Drug Class**: Antihistamines – 2nd 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)
Clarinex®
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
Tarka® tablet
trandolapril / verapamil tablet

**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

## 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 Colcrys)
probenecid/colchicine tablet
probenecid tablet

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

colchicine capsules (generic for Mitigare)
Colcrys (colchicine) tablet
febuxostat 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 - OTHER

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

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

Nurtec ODT®

**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

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

Elyxyb®
Reyvow®
Ubrelvy®

**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 per 30 days
**REYVOW® (LASMIDITAN)** – Quantity Limit: 8 tablets per 30 days
**UBRELVY® (UBROGEPANT)** – Quantity Limit: 16 tablets per 30 days

❒ **Duration of Approval**: 1 year

## ANTIMIGRAINE AGENTS, ACUTE TREATMENT - TRIPTANS

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

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

Imitrex® nasal spray
rizatriptan tab and ODT
sumatriptan tablets, injection

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

almotriptan
Amerge®
eletriptan
Frova®
frovatriptan
Imitrex®
naratriptan
Maxalt®/ Maxalt MLT®
Onzetra Xsail®
Relpax®
sumatriptan-naproxen
sumatriptan nasal spray
Tosymra®
Treximet®
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
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Therapeutic failure with treatment for three migraine episodes with use of two (each agent should be tried for three episodes) of the preferred agents

**QUANTITY LIMITS**

| | |
|---|---|
| almotriptan (Axert) | 9 per fill |
| Amerge® (naratriptan) | 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 |
| Imitrex® Nasal Spray (sumatriptan) | 6 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 (Imitrex®, Tosymra®) | 6 per fill |
| zolmitriptan (Zomig®/ Zomig ZMT®) | 12 per fill |
| Zomig®/Zomig ZMT® (zolmitriptan) | 12 per fill |

❒ **Duration of Approval**: 6 months

## ANTIMIGRAINE AGENTS, PREVENTIVE TREATMENT

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

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

Aimovig®
Emgality®
Nurtec ODT®

**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; **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*

Ajovy®
Qulipta®

**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 AGENTS

**Drug Class**: Anti-Obesity Agents

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

**Pancreatic Lipase Inhibitors:**
Xenical (orlistat)
orlistat

**GLP-1 Agonists:**
Saxenda (liraglutide*)*
Wegovy (semaglutide)

**Combination Products:**
Contrave (bupropion/naltrexone)

**Noradrenergic Sympathomimetic Agents:**
benzphetamine (only available as generic); C-III
diethylpropion (only available as generic); C-IV
Adipex-P (phentermine); C-IV
Lomaira (phentermine); C-IV
phentermine; C-IV
phendimetrazine (only available as generic); C-III

**Clinical Prior Authorization**

**Initial**

- Patient must have a body mass index [BMI] ≥ than 30 kg/m$^2$; **OR**
- Patient must have a body mass index [BMI] ≥ than 27 kg/m$^2$ but <30 kg/m$^2$ and at least one of the following risk factors:
  - hypertension, coronary artery disease, diabetes, dyslipidemia, or sleep apnea; **AND**
- Patient age ≥12 years (Xenical, Saxenda); **OR**
- Patient age ≥18 years (Wegovy, Contrave, benzphetamine, diethylpropion, phentermine, phendimetrazine); **AND**
- Prescriber attests to patient's absence of any contraindications to use of the requested product; **AND**
- Prescriber attests that the patient is not pregnant or lactating; **AND**
- Prescriber attests that at least one previously documented weight reduction attempt in the past year; **AND**
- Prescriber attests medication therapy is part of a total treatment plan including a calorie and fat restricted diet and exercise regimen.

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

**Renewal**

- Prescriber attests that patient has maintained a weight loss of ≥ 5% from baseline weight at initiation of therapy.
- Length of approval for both initial and renewal: 6 months

❒ **Duration of Approval**: 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
Kynmobi®
Mirapex ER®
Neupro®
Parlodel®
pramiprexole ER
Requip®
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:**

**KYNMOBI® (*APOMORPHINE*)**

- Patient is experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements) despite optimized oral Parkinson's therapy; **AND**
- Patient is currently receiving levodopa and adjunctive therapy with anti-Parkinson's agents
- Patient is NOT concurrently taking a 5-HT3 antagonist [i.e., Zofran® (ondansetron), Kytril® (granisetron), Anzemet® (dolasetron), Aloxi® (palonosetron), and Lotronex® (alosetron)]; **AND**
- Patient has a concurrent prescription order for trimethobenzamide to pre-medicate for the initial doses of apomorphine as needed

**NEUPRO® *(ROTIGOTINE)***

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

❒ **Duration of Approval**: 1 year

## ANTIPARKINSON'S AGENTS – OTHER

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

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

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

**RASAGILINE** *(AZILECT®)*
- Patient is >18 years of age

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

amantadine tablet
Azilect®
carbidopa
carbidopa tablet / levodopa ODT
carbidopa/levodopa/entacapone tablet
Comtan®
Dhivy®
Duopa®
entacapone
Gocovri®
Inbrija®
Lodosyn®
Nourianz®
Ongentys®
Osmolex ER®
Rytary®
selegiline capsule, tablet
Sinemet®
Stalevo®
Tasmar®
tolcapone
trihexyphenidyl elixir (*Carve Out)
Xadago®
Zelapar®

**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

**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

***Carved Out- Bill Fee-For-Service Medicaid**
**(See MPPL @ michigan.magellanrx.com for coverage details)**

**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® (*CARBIDOPA/LEVODOPA*)**

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

**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

## ANTIVIRALS – HERPES

**Drug Class**: Antivirals – Herpes

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

acyclovir tablets, capsules, suspension
famciclovir tablet
valacyclovir tablet

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

Sitavig® tablet
Valtrex® caplet
Zovirax® suspension

**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 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
Xofluza®

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

Flumadine®
Tamiflu®

**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 *(oseltamivir) – 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 ointment
Denavir®
Zovirax® cream

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

acyclovir cream
penciclovir (generic for Denavir)
Xerese®
Zovirax® ointment

**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

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

- ❒ **Diagnoses**: Diagnosis of chorea associated with Huntington's disease; **OR** 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):
  - 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 that a follow-up AIMS test has been completed and there has been a positive response to therapy

# 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.[1]
  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.[2]

**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)
Utibron Neohaler® (DPI)

**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
- The patient's condition is clinically stable such that switching medications would cause deterioration in the condition
- 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)
budesonide/formoterol (generic for Symbicort)
Fluticasone/Vilanterol (generic for Breo Ellipta)
fluticasone/salmeterol (generic for Advair Diskus)
fluticasone/salmeterol (generic for AirDuo)
Wixela® (DPI) (generic for Advair Diskus)

**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 a two-week trial with one preferred medication

❒ **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*

Arcapta® (DPI)
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
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- 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 sulfate nebulizer solution
ProAir HFA® (MDI)
Proventil HFA® (MDI)
Ventolin HFA® (MDI)

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

albuterol HFA (MDI)
levalbuterol HFA (MDI)
levalbuterol nebulizer solution
ProAir Digihaler® (DPI)
ProAir Respiclick® (DPI)
Xopenex HFA® (MDI)
Xopenex® nebulizer 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
- Therapeutic failure after a two-week trial with one preferred medication

❒ **Duration of Approval**: 1 year

# BETA BLOCKERS

**Drug Class**: Beta Blockers

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

atenolol
atenolol / chlorthalidone
bisoprolol fumarate HCT
Bystolic®
carvedilol
labetalol
metoprolol / metoprolol XL
metoprolol succinate
metoprolol tartrate
propranolol / propranolol LA
Sorine tablet®
sotalol / sotalol AF

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

acebutolol
Betapace® / Betapace AF®
betaxolol
bisoprolol fumarate
Coreg® tablet / Coreg CR®
Corgard®
Corzide®
Hemangeol oral solution®
Inderal LA®/ Inderal XL®
Innopran XL®
Kapspargo®
Lopressor®
metoprolol HCT
nadolol
nadolol/bendroflumethiazide
nebivolol
pindolol
propranolol HCT
Sotylize®
Tenormin®/ Tenoretic®
timolol maleate
Toprol XL®
Ziac®

**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

## 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®/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

# BIOLOGIC IMMUNOMODULATORS

**Drug Classes**:

- ❒ Agents to Non-radiographic Axial Spondyloarthritis
- ❒ Agents to Treat Ankylosing Spondylitis
- ❒ Agents to Treat Crohn's Disease
- ❒ Agents to Treat Juvenile Idiopathic Arthritis
- ❒ Agents to Treat Plaque Psoriasis
- ❒ Agents to Treat Psoriatic Arthritis
- ❒ Agents to Treat Rheumatoid Arthritis
- ❒ Agents to Treat Ulcerative Colitis

## ❖ AGENTS TO TREAT NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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

Cosentyx®

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

Cimzia®, Cimzia Kit®
Rinvoq ER®
Taltz®

## ❖ AGENTS TO TREAT ANKYLOSING SPONDYLITIS

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

Cosentyx®
Enbrel®
Humira®

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

Cimzia®, Cimzia Kit®
Rinvoq ER®
Simponi®, Simponi Aria®
Taltz®
Xeljanz®, Xeljanz XR®

## ❖ AGENTS TO TREAT CROHN'S DISEASE

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

Humira®

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

Cimzia®, Cimzia Kit®
Entyvio®
Skyrizi®
Stelara®

## ❖ AGENTS TO TREAT JUVENILE IDIOPATHIC ARTHRITIS

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

Enbrel®
Humira®

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

Actemra® SC
Orencia® SC
Simponi ARIA®
Xeljanz®, Xeljanz Solution

## ❖ AGENTS TO TREAT PLAQUE PSORIASIS

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

Cosentyx®
Enbrel®
Humira®

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

Cimzia®, Cimzia Kit®
Ilumya®
Otezla®
Siliq®
Skyrizi®
Stelara®
Taltz®
Tremfya®

## ❖ AGENTS TO TREAT PSORIATIC ARTHRITIS

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

Cosentyx®
Enbrel®
Humira®

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

Cimzia®, Cimzia Kit®
Orencia® SC
Otezla®
Rinvoq ER®
Simponi®, Simponi Aria®
Skyrizi®
Stelara®
Taltz®
Tremfya®
Xeljanz®, Xeljanz XR®

## ❖ AGENTS TO TREAT RHEUMATOID ARTHRITIS

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

Enbrel®
Humira®

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

Actemra® SC
Cimzia®, Cimzia Kit®
Kevzara®
Kineret®
Olumiant®
Orencia® SC
Rinvoq ER®
Xeljanz®, Xeljanz XR®
Simponi®, Simponi Aria®

## ❖ AGENTS TO TREAT ULCERATIVE COLITIS

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

Humira®

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

Entyvio®
Rinvoq ER®
Simponi®
Stelara®
Xeljanz®, Xeljanz XR®

**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:**

## Medication-Specific Criteria

**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 (Asacol®HD, Pentasa®, Lialda®, Apriso®, 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®, etanercept (Enbrel®)]
    - **Length of authorization**: Initial approval = 14 weeks; renewal = 1 year

**ILUMYA® (*TILDRAKIZUMAB*)**

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

**KEVZARA® (*SARILUMAB*)**

- Diagnosis of moderately to severely active rheumatoid arthritis (RA); **AND**
- Patient must be 18 years or older

**OLUMIANT® *(BARICITINIB)*** (PDL criteria do not apply)

- For diagnosis of severe alopecia areata; **AND**
- Patient must be 18 years or older

**OTEZLA® (*APREMILAST*)**

- Diagnosis of psoriatic arthritis with 3 or more swollen and tender joints; **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; **AND**

**RINVOQ ER® (*UPADACITINIB)***
- Diagnosis of moderate to severe rheumatoid arthritis; **OR**
- Diagnosis of ankylosing spondylitis**; OR**
- Diagnosis of psoriatic arthritis; **OR**
- Diagnosis of non-radiographic axial spondyloarthritis; **OR**
- Diagnosis of moderately to severely active ulcerative colitis**; AND**
- Patient must be 18 years or older

**SILIQ® (*BRODALUMAB*)**
- Diagnosis of plaque psoriasis; **AND**
- Patient must be 18 years or older

**SKYRIZI® (*RISANKIZUMAB*)**
- 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; **AND**
- Prescribed by or in consultation with a gastroenterologist or rheumatologist

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

**XELJANZ® (*TOFACITINIB*)**
- Diagnosis of rheumatoid arthritis (RA) or psoriatic arthritis (PsA), or polyarticular juvenile idiopathic arthritis (pJIA) or ankylosing spondylitis (AS); **AND**
    - Failure or inadequate response to methotrexate; **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
- Xeljanz Solution is only approved for Polyarticular Course Juvenile Idiopathic Arthritis (pJIA)

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

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

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

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

Dutasteride capsule
finasteride 5mg tablet (generic for Proscar®)

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

Avodart® softgel
dutasteride/tamsulosin capsule
Jalyn® capsule
Proscar® tablet

**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 a one-month trial with one preferred medication

❒ **Duration of Approval**: 1 year

## 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

**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 a one-month trial with one preferred medication

❒ **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:** *No Prior Authorization required*

amlodipine besylate tablet
nifedipine tablet / nifedipine SA tablet

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

Adalat CC® tablet
felodipine ER tablet
isradipine capsule
Katerzia® suspension
levamlodipine
Nicardipine capsule
nisoldipine tablet
Norliqva®
Norvasc® tablet
Procardia capsule / Procardia XL® tablet
Sular® 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**
- 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
- Allow if patient has swallowing difficulties

**NORLIQVA® SUSPENSION *(AMLODIPINE)***

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

❒ **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*

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

**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

## 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 ≥ 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**: ≥ 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 ≥ 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
Keflex®

## ❖ 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
cefixime capsules
Suprax® capsules

## ❖ CEPHALOSPORINS - 3RD GENERATION, continued

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

cefixime suspension
cefpodoxime tablets
cefpodoxime suspension
Suprax® chew tabs, suspension

**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
- Infection caused by an organism resistant to the preferred cephalosporins
- Therapeutic failure (duration = 3 days) with any two preferred cephalosporins medications

**QUANTITY LIMITS**

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

❒ **Duration of Approval**: Date of service

## COLONY STIMULATING FACTORS

**Drug Class**: Colony Stimulating Factors

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

Neupogen®
Nyvepria®

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

Fulphila®
Granix®
Leukine®
Neulasta® syringe; Neulasta® Onpro Kit
Nivestym®
Releuko®
Udenyca®
Zarxio®
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:**

| | |
|---|---|
| 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 |
| Fulphila 6mg/0.6ml Syringe | 0.6 mls per 14 days |
| Udenyca 6mg/0.6ml Syringe | 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*

Acanya® gel and pump
Neuac 1.25% kit®
Onexton®

**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

# 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 ≤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. Accessed September 25, 2015.

**References, continued**

2. Thomas CF, Limper AH. Treatment and prevention of Pneumocystis pneumonia in non-HIV-infected patients. Waltham, MA: UptoDate; Last modified January 6, 2015. http://www.uptodate.com/contents/treatment-and-prevention-of-pneumocystis-pneumonia-in-non-hiv-infected-patients?source=search_result&search=pneumocystis&selectedTitle=4%7E150. Accessed September 25, 2015.
3. Sax PE. Treatment and prevention of Pneumocystis infection in HIV-infected patients. Waltham, MA: UptoDate; Last modified August 27, 2015. http://www.uptodate.com/contents/treatment-and-prevention-of-pneumocystis-infection-in-hiv-infected-patients?source=search_result&search=pneumocystis&selectedTitle=2%7E150#H2384560994. Accessed September 25, 2015.

## DESMOPRESSIN / STIMATE NASAL SPRAY

**Drug Class:** Antidiuretic and vasopressor hormones

**FDA-approved uses:**

Diabetes Insipidus – 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**:

- Diabetes Insipidus

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

- Documentation of a Diabetes Insipidus
- Documented inadequate response to a 3-month trial of a maximum tolerated dose or clinical contraindication of Desmopressin tablets

**Route of Administration:** various

**Contraindications/Exclusions/Discontinuation:**

- Contraindicated in individuals with known hypersensitivity to desmopressin acetate or to any of its components.
- Contraindicated in patients with moderate to severe renal impairment (defined as a creatinine clearance below 50ml/min).
- Contraindicated in patients with hyponatremia or a history of hyponatremia.
- 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.
    - As of 2007, the intranasal formulation is no longer FDA-approved for the treatment of primary nocturnal enuresis.

## DIRECT RENIN INHIBITORS

**Drug Class**: Direct Renin Inhibitors

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

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

aliskiren
Tekturna® / Tekturna HCT®

**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

## DOVONEX® / CALCIPOTRIENE

**Drug Class:** Dermatological - Antipsoriatics

**FDA-approved uses:** The relief of Psoriasis

**Available dosage forms:** 0.005% Cream, Ointment and Solution

**Coverage Criteria/Limitations for initial authorization**

- ❒ **Diagnoses:** Psoriasis
- ❒ **Duration of Approval**
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 6 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of Psoriasis
  - Failure of two Topical Steroids, at least one of which must be high potency or very high potency
- ❒ **Route of Administration:** For Topical Use Only

**Criteria for continuation of therapy:**

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Requires a positive response to therapy

**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

## ELECTROLYTE DEPLETERS

**Drug Class**: Electrolyte 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®
Eliphos®
Fosrenol® / Fosrenol® powder pak
lanthanum
Phoslo®
Phoslyra®
Renagel®
Renvela powder pkts and tablets
sevelamer carbonate powder pkts (generic for Renvela)
sevelamer tablets (generic for Renagel)
Velphoro®

**Non-Preferred Agent PA Criteria:**

- Diagnosis of chronic kidney disease
- 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 with one preferred medication

**VELPHORO®**

- Trial on **two** preferred medications.

❒ **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)

## EPINEPHRINE INJECTABLE

**Drug Class**: Epinephrine Injectable

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

Epi Pen®, Epi Pen Jr®

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

epinephrine (generic for Adrenaclick®)
epinephrine (generic for Epi Pen®)
Symjepi®

**Non-Preferred Agent PA Criteria:**

- Therapeutic failure with preferred medication

**QUANTITY LIMITS**

| | |
|---|---|
| Adrenaclick® (epinephrine) | 4 per fill |
| epinephrine | 4 per fill |
| Epipen® (epinephrine) | 4 per fill |
| Epipen Jr® (epinephrine) | 4 per fill |

❒ **Duration of Approval**: 1 year

# EXSERVAN FILM, TIGLUTIK SUSPENSION / RILUZOLE

**Drug Class**: ALS Agent - Benzathiazoles

**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

## EYSUSVIS LOTEPREDNOL

**Drug Class**: Ophthalmic - Anti-inflammatory, Glucocorticoids

**FDA-approved uses**: Dry Eye Disease

**Available dosage forms**: 0.25% ophthalmic suspension

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

- ❒ **Diagnoses**: Dry Eye Disease (DED)
- ❒ **Duration of approval**:
  - **Initial authorization**: 2 weeks
  - **Continuation of Therapy**: 2 weeks
- ❒ **Prescriber Specialty**: Prescribed by an ophthalmologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient does NOT have viral diseases of the cornea and conjunctiva (e.g., epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, and varicella), mycobacterial infection of the eye, or fungal diseases of ocular structures; **AND**
  - Patient has trial and failure of an ocular lubricant (e.g., artificial tears), including preservative-free formulation; **AND**
  - Prescriber attestation that causative factors cannot be mitigated
  - Trial and failure of a generic ophthalmic steroid
  - Current dry eye flare up
- ❒ **Quantity**: 8.3ml (in a 10ml bottle) per fill (14 days)
- ❒ **Age**: ≥ 18 Years old
- ❒ **Route of Administration**: ophthalmic

**Criteria for continuation of therapy**:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Patient continues to meet criteria above; **AND**
  - Patient has had an examination under magnification (e.g., slit lamp) and evaluation of the intraocular pressure (IOP); **AND**
  - Absence of unacceptable toxicity from the drug (e.g., infection, delayed healing, corneal or scleral thinning, increased IOP, cataracts); **AND**
  - Patient is NOT a candidate for long-term treatment or alternative therapies (e.g., punctal occlusion, ophthalmic immunomodulators); **AND**
  - Attestation of improved that signs and symptoms of DED has improved, but continued treatment is needed

**Contraindications/Exclusions/Discontinuation**:

- have viral diseases of the cornea and conjunctiva (e.g., epithelial herpes simplex keratitis [dendritic keratitis], vaccinia, and varicella)
- mycobacterial infection of the eye
- fungal diseases of ocular structures

## GASTROINTESTINAL ANTIBIOTICS

**Drug Class**: Gastrointestinal Antibiotics

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

Firvanq®
metronidazole tablets
neomycin tablets
tinidazole
vancomycin capsules

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

Aemcolo®
Dificid®
Flagyl® tablets and capsules
metronidazole capsules
nitazoxanide tablets
Vancocin®
vancomycin solution
Xifaxan® 200mg
Xifaxan® 550mg

**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
- **Length of authorization: 3 days**

**DIFICID® (*FIDAXOMICIN*)**

- C. difficile **and** 10-day trial of oral vancomycin or contraindication.
- **Length of authorization = 30 days**

**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)

**XIFAXAN® (*RIFAXIMIN)*** (PDL criteria do not apply)

- 200 mg tabs:
  - Travelers' diarrhea caused by noninvasive strains of *E. coli* and age ≥ 12 years of age
  - The patient has had an inadequate response, intolerance, or contraindication to azithromycin or a fluoroquinolone.

- 550 mg tabs:
  - Reduction in risk of overt hepatic encephalopathy recurrence in patients ≥ 18 years of age (PDL criteria do not apply)
  - Diagnosis of irritable bowel syndrome with diarrhea (IBS-D) in patients ≥18 years of age (PDL criteria do not apply)

❒ **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:**

Amitiza® capsule
Linzess® capsule

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

Motegrity® tablet
Trulance® tablet
lubiprostone capsule (generic Amitiza®)

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

**Preferred Agents:**

Amitiza® capsule
Linzess® capsule

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

Ibsrela®
Trulance® tablet
lubiprostone capsule (generic Amitiza®)

## ❖ 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 tablet
Lotronex® tablet
Viberzi® tablet

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

**Preferred Agents:**

Amitiza® capsule
Movantik®

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

Relistor® syringe, vial
Symproic® tablet
lubiprostone capsule (generic Amitiza®)

## 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**
- **See additional medication-specific criteria below:**

## Medication-Specific Criteria

**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

**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

**RELISTOR® (*METHYLNALTREXONE*)**

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

**SYMPROIC® (*NALDEMEDINE TOSYLATE*)**

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

**TRULANCE® (*PLECANATIDE*)**

- Diagnosis of chronic idiopathic constipation (CIC) or irritable bowel syndrome with constipation (IBS-C); **AND**
- Therapeutic failure after one-month trial of one preferred agent for CIC or IBS-C

**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 0.15%
Iopidine®

## ❖ 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 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*

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

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

Brinzolamide
Cosopt®/ Cosopt PF®
dorzolamide / timolol PF (generic for Cosopt PF®)
Trusopt®

## ❖ 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®)
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

## GLUCAGON AGENTS

**Drug Class**: Glucagon Agents

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

Baqsimi®
Glucagen Hypokit
Glucagon Emergency Kit (Lilly)
Gvoke Pen®

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

Glucagon Emergency Kit (Fresenius)
Gvoke® Syringe, Kit, Vial
Zegalogue®

**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®

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

Humatrope®
Nutropin AQ®
Omnitrope®
Saizen®
Serostim®
Skytrofa®
Zomacton®
Zorbtive®

**PA Criteria:**

- Allergy to inactive ingredients in the preferred medications
- Requests must be submitted by an endocrinologist or nephrologist.
- Panhypopituitarism – Cachexia, pituitary; Necrosis of pituitary (postpartum); Pituitary insufficiency NOS; Sheehan's syndrome; Simmond's disease.
- 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 pseudohermaphroditism – Gynandrism; Hermaphroditism; Ovotestis; Pseudohermaphroditism (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:**
  - 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.
  - 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):**
  - 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.
  - 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.

❒ **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*

lansoprazole/amoxicillin/clarithromycin
Omeclamox-PAK®
Talicia

**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 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*

Procrit®

**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 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®, PROCRIT®, 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®, PROCRIT®, 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®, PROCRIT®, RETACRIT® AND ARANESP® ONLY):**

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

**ANEMIA IN AIDS PATIENTS: (EPOGEN®, PROCRIT®, RETACRIT® ONLY)**

- Hemoglobin level < 10 g/dL

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

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

**MYELODYSPLASIA AND MYELODYSPLASTIC SYNDROME (EPOGEN®, PROCRIT®, RETACRIT® ONLY):**

- CURRENT hemoglobin level < 10 g/dL

**HEPATITIS C WITH CURRENT INTERFERON TREATMENT (EPOGEN®, PROCRIT®, RETACRIT® ONLY):**

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

❒ **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 ≥ 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 ≥ 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- ASTHMA

**Drug Class**: Immunomodulators- Asthma

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

Dupixent®
Xolair® Syringe

**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)*:**
***For Atopic Dermatitis diagnoses please refer to the Immunomodulators – Atopic Dermatitis PDL class criteria**

- 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 ≥ 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 **OR**
- 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; **OR**
- Diagnosis of eosinophilic esophagitis (EoE) ; **AND**
  - Patient ≥12 years old; **AND**
  - Patient weighs ≥ 40 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; **OR**
- Diagnosis of prurigo nodularis (PN); **AND**
  - Patient ≥18 years old; **AND**
  - Prescribed by or in consultation with an allergist, immunologist, or dermatologist

**XOLAIR® *(OMALIZUMAB)***

- Moderate to severe 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 ≥ 30 IU/ml; **OR**
- 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; **OR**
- Diagnosis of 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; **OR**

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

Fasenra® Pen
Nucala® Syringe, Autoinjector

**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:**

**FASENRA (BENRALIZUMAB):**

- Patient must have severe asthma; **AND**
- Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months; **AND**
- Patient must be 12 years of age or older

**NUCALA (MEPOLIZUMAB):**

- Patient must have severe asthma; **AND**
    - Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months; **AND**
    - Patient must be 6 years of age or older; **OR**
- 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; **OR**
- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) *(PDL CRITERIA DO NOT APPLY)* **AND**
    - Patient ≥ 18 years old; **OR**
- Diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause *(PDL CRITERIA DO NOT APPLY)* **AND**
    - Patient must be 12 years of age or older

❒ **Duration of Approval**: 1 year

*Only products that can be self-administered will be included in the PDL class as other products are typically billed as a medical benefit

## IMMUNOMODULATORS: ATOPIC DERMATITIS

**Drug Class**: Immunomodulators: Atopic Dermatitis

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

Dupixent®
Elidel®
Eucrisa®

**Clinical PA Criteria:**

- Diagnosis of atopic dermatitis
- Dupixent®: moderate to severe for ages ≥ 6 months old
- **Elidel®**: mild to moderate for ages ≥ 2 years
- **Eucrisa®:** mild to moderate for ages ≥ 3 months

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

Adbry®
Cibinqo®
Opzelura®
Pimecrolimus (generic for Elidel)
Protopic®
Rinvoq ER®
Tacrolimus

**Non-Preferred Agent PA Criteria:**

- Diagnosis of atopic dermatitis
- Allergy to the preferred medication(s)**; 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
- Additional disease severity and age limits:
    - **Pimecrolimus** – PDL Brand Preferred Over Generic, must use Elidel® cream
    - **Rinvoq ER®** moderate to severe for ages ≥ 12 years
    - **Tacrolimus/Protopic®** 0.03%: moderate to severe for ages ≥ 2 years
    - **Tacrolimus/Protopic®** 0.1%: moderate to severe for ages ≥ 16 years
- **See additional medication-specific criteria below:**

**ADBRY® (*TRALOKINUMAB-LDRM*)**

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient age ≥18 years old
- Quantity limit: 4 syringes per 28 days (with special allowance for initial dose)

**CIBINQO® *(ABROCITINIB)***

- Diagnosis of moderate to severe atopic dermatitis; **AND**
- Patient age ≥18 years old

**DUPIXENT® (*DUPILUMAB*)**

***For Asthma diagnoses please refer to the Immunomodulators – Asthma PDL class criteria**

- 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.
- Diagnosis of moderate to severe atopic dermatitis **AND**
  - **Patient** ≥ 6 months old; **OR**
- Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP); **AND**
  - Patient ≥ 18 years old
  - Patient has inadequate response after 3 consistent months use of intranasal steroids or oral corticosteroids; **AND**
  - Patient is concurrently treated with intranasal corticosteroids; **OR**
- Diagnosis of eosinophilic esophagitis (EoE) ; **AND**
  - Patient ≥12 years old; **AND**
  - Patient weighs ≥ 40 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; **OR**
- Diagnosis of prurigo nodularis (PN); **AND**
  - Patient ≥18 years old; **AND**
  - Prescribed by or in consultation with a allergist, immunologist, or dermatologist
- Length of authorization: 1 year

**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 ≥ 12 years old**; OR**
- Diagnosis of nonsegmental vitiligo; **AND**
  - Bypass PDL criteria; **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

**QUANTITY LIMITS**

| | |
|---|---|
| Adbry® (tralokinumab-ldrm) | 4 syringes per 28 days (with special allowance for initial dose) |
| Elidel® (pimecrolimus) | 30gm per 30 days |
| Eucrisa® (crisaborole) | 100 gm per 30 days |
| Opzelura® (ruxolitinib phosphate) | 240gm (4 x 60gm) per 30 days |
| Protopic® (tacrolimus) | 30gm per 30 days |

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

## INCRELEX® / MECASERMIN

***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:** Insulin like growth factor 1 hormones

**FDA-approved uses:**

- ❒ Severe primary IGF-1 deficiency:
  - mutation in the GH-receptor
  - mutation in the post-GHR signaling pathway
  - IGF-1 gene defects
- ❒ Growth hormone gene deletion and have developed neutralizing antibodies to growth hormone

**Available dosage forms:** 10mg/ml multi-dose vial (40mg/ vial)
**Recommended Dosage:** Dosage of mecasermin should be individualized for each patient.

- ❒ The recommended starting dose of Increlex® is 0.04–0.08 mg/kg twice daily by subcutaneous injection.
- ❒ If well-tolerated for at least one week, the dose may be increased by 0.04 mg/kg per dose, to the maximum dose of 0.12 mg/kg given twice daily.

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

- ❒ **Diagnoses**: Member has **ONE** of the following diagnoses:
  - Severe primary IGF-1 deficiency:
    - mutation in the GH-receptor
    - mutation in the post-GHR signaling pathway
    - IGF-1 gene defects
  - Growth hormone gene deletion and have developed neutralizing antibodies to growth hormone
- ❒ **Prescriber Specialty:** endocrinologist or pediatric endocrinologist.
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, and Special Studies):
  *Documentation of **ALL** of the following is required*:
  - Current height measurement at less than the 3rd percentile for age and sex
  - IGF-1 level greater than or equal to 3 standard deviations below normal (based on lab reference range for age and sex)
  - For Primary IGFD:
    - Normal or elevated growth hormone levels (Stimulation testing is not required when levels are normal or high).
      **Exception: Diagnosis of growth hormone gene deletion.*
  - Epiphyses must be confirmed as open for members age 10 and older (submit radiograph report).
  - Parental height (height of each parent, if available, or explanation of why not available – such as child adopted, or one parent no longer involved and is unavailable for measurement)

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, and Special Studies):
  *Documentation of **ALL** of the following is required*:-**Continued –**
    - Clinically determined growth failure as defined by abnormally low growth rate velocity
      - Abnormal growth velocity is defined by the following:
        - A history of lower than normal growth velocity, as shown by growth charts spanning at least 6 months of time, **and**
        - Height: Baseline height must be < the 3rd percentile or > 2 standard deviations [SD] below the mean for gender and age, a measure of the degree of short stature.
      - Prescriber to submit member's height and weight measurements:
        - These measurements must be logged in a table and plotted on standard CDC growth chart.
        - Height and weight measures must cover at least a one-year time-span* **Exception: If a member is in puberty, bone age may be advancing secondary to sex hormone production. If previous growth data cannot be found to provide the "one-year" or longer time-span of data, then sexual maturity rating (Tanner Staging) and measurement of sex hormones may be submitted with only 6 months of growth data.*
- ❒ **Age**: Member is > 2 years and < 18 years of age

**Contraindications/Exclusions/Discontinuation:**

- Closed epiphyses
- Active or suspected neoplasia
- Allergy to mecasermin (IGF-1) or any of the inactive ingredients in mecasermin
- Intravenous (IV) administration
- 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**: Member is not receiving concurrent growth hormone therapy **or** pharmacologic doses of corticosteroids.

# INCRETIN MIMETICS AND COMBINATIONS

**Drug Class**:

- ❒ Incretin Mimetics
- ❒ Incretin Mimetics - Combinations

## ❖ INCRETIN MIMETICS

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

Byetta®
Trulicity®
Victoza®

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

Adlyxin®
Bydureon Bcise®
Mounjaro®
Ozempic®
Rybelsus®

## ❖ INCRETIN MIMETICS – COMBINATIONS

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

Soliqua®
Xultophy®

**Non-Preferred Agent PA Criteria:**

- Diagnosis of type 2 diabetes; **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:**

**OZEMPIC® (SEMAGLUTIDE)**

- Trial and failure of a Preferred Medication is not required for members already established on Ozempic as it is indicated for both improved cardiovascular outcomes and once weekly administration.

**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)

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

## INGREZZA / VALBENAZINE

**Drug Class** Movement Disorder Therapy - Tardive Dyskinesia

**FDA-approved uses**: Tardive Dyskinesia

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

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

- ❒ **Diagnoses**: 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):
  - 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 that a follow-up AIMS test has been completed and there has been a positive response to therapy

## INHALED GLUCOCORTICOIDS

**Drug Class**: Inhaled Glucocorticoids

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

Asmanex® Twisthaler (DPI)
budesonide 0.25 and 0.5mg nebulizer solution
budesonide 1mg nebulizer solution (generic for Pulmicort Respules)
Flovent HFA® (MDI)

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

Alvesco® (MDI)
Arnuity Ellipta® (DPI)
Armonair Digihaler
Asmanex HFA® (DPI)
Flovent Diskus® (DPI)
Fluticasone Prop HFA (Generic Flovent HFA)
Pulmicort Flexihaler® (DPI)
Pulmicort® 1mg Respules nebulizer solution
Pulmicort® 0.25mg and 0.5mg Respules
QVAR Redihaler® (MDI)

**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 a two-week trial with two preferred medications
- 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:**

**ALVESCO® *(CICLESONIDE)***

- Requests submitted referencing exception due to compatibility with spacer/chamber will require trial only on Flovent® HFA

**ASMANEX® HFA *(MOMETASONE)***

- Requests submitted referencing exception due to compatibility with spacer/chamber will require trial only on Flovent® HFA

**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

**ARNUITY ELLIPTA® *(FLUTICASONE)***

- Therapeutic failure on all preferred agents

**PULMICORT FLEXHALER® *(BUDESONIDE)***

- Pregnancy (approval for duration of pregnancy)

❒ **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 pens, vials
Humalog® 75/25 pens, vials
Humulin® 70/30 Kwikpens, vials
insulin aspart 70/30 vials
Novolog® 70/30 pens

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

insulin aspart 70/30 pens
insulin lispro mix 75-25 Kwikpen
Novolin® 70/30 pens, vials
Novolog® 70/30 vials

## ❖ 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
Semglee® pens , vials
insulin glargine-YFGN pens , vials (biosimilar for Semglee®)
insulin glargine Solostar U100 pens, vials (biosimilar for Lantus®)
Toujeo Solostar® pens
Tresiba Flextouch® pens, vials
insulin degludec pens, vials

## ❖ INSULINS, RAPID ACTING

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

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

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

Admelog® vials; Admelog Solostar® pens
Afrezza® inhalation cartridges
Fiasp® pens, vials
Humalog® U-200 Kwikpens
insulin aspart cartridges, pens, vials
Lyumjev®, Kwikpens, Tempo Pens

## ❖ INSULINS, TRADITIONAL

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

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

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

Humulin® N Kwikpens

**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 within same subgroup
- **See additional medication-specific criteria below:**

**LYUMJEV™ (*INSULIN LISPRO-AABC*)**

- Quantity limit = 90 per fill

**TOUJEO SOLOSTAR® *(INSULIN GLARGINE)***

- Trial and failure on both preferred medications in this class

❒ **Duration of Approval**: 1 year

# ISOTRETINOIN / CLARAVIS®
# ISOTRETINOIN / AMNESTEEM®
# ISOTRETINOIN / MYORISAN™
# ISOTRETINOIN / ZENATANE™

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

**FDA-approved uses:** Treatment of severe (multiple locations) recalcitrant nodular acne unresponsive to conventional therapy including conventional antibiotics

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

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

- ❒ **Diagnoses:** severe (multiple locations) recalcitrant nodular acne unresponsive to conventional therapy including conventional antibiotics
- ❒ **Duration of Approval**
  - **Initial Authorization:** 5 months, with monthly office visits
  - **Continuation of Therapy:** Reviewed for coverage after a period of 2 months or more off therapy, and if warranted by persistent or recurring severe nodular acne
- ❒ **Prescriber Specialty:** Dermatologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Proper diagnosis of an FDA approved indication **OR**
  - If request is for a non-FDA Approved indication, the request must be for a "medically accepted indication" as noted in the following Compendia:
    - American Hospital Formulary Drug Service (AHFS-DI)
    - Micromedex DrugDex
    - Clinical Pharmacology
  - Must be prescribed by a dermatologist
  - Current chart notes detailing the diagnosis, including laboratory tests as appropriate for diagnosis
  - Documentation of dose, dates of therapy, and clinical outcomes as appropriate
  - Failed/intolerant to at least 2 oral antibiotics (must have used consistently for 6 months)
  - Failed/intolerant to topical retinoid product (must have used consistently for 6 months)
  - Failed/intolerant to Benzoyl Peroxide wash (must have used consistently for 6 months)
  - Failed/intolerant to Clindamycin and/or Erythromycin topical therapy (must have used consistently for 6 months)
  - Negative pregnancy test
  - Must select 2 forms of effective contraception simultaneously
  - Must meet requirements of the iPledge Program

- ❒ **Not approved If:**
  - Patient has any contraindications to the use of isotretinoin
  - Patient is not compliant with current therapy

- ❒ **Dosing:**
  - ***Adult Acne, severe recalcitrant nodular:***
    - Oral: 0.5-1 mg/kg/day in 2 divided doses for 15-20 weeks
    - May discontinue earlier if the total cyst count decreases by 70%
    - Adults with very severe disease/scarring or primarily involves the trunk may require dosage adjustment up to 2 mg/kg/day
    - A second course of therapy may be initiated after a period of ≥ 2 months off therapy
    - A dose of ≤0.5 mg/kg/day may be used to minimize initial flaring
  - ***Pediatric Acne, severe recalcitrant nodular:***
    - Children 12-17 years:
      - Oral: 0.5-1 mg/kg/day in 2 divided doses for 15-20 weeks
      - May discontinue earlier if the total cyst count decreases by 70%
      - A second course of therapy may be initiated after a period of ≥ 2 months off therapy
      - A dose of ≤0.5 mg/kg/day may be used to minimize initial flaring
- ❒ **Age:** 12 years and older
- ❒ **Route of Administration:** Oral

**Criteria for continuation of therapy:**

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Office visit every month with verified compliance and improvement or stability on drug

**Contraindications/Exclusions/Discontinuation:**

- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable of improvement in clinical condition has occurred after initiation of drug therapy

**References:**


a. American Academy of Pediatrics Committee on Drugs, "Retinoid Therapy for Severe Dermatological Disorders," *Pediatrics*, 1992, 90(1 Pt 1):119-20.
b. Claravis [package insert]. Sellersville PA: Teva Pharmaceuticals USA; January 2015.
c. Facts & Comparisons. (2012). Claravis. Retrieved from http://0-online.factsandcomparisons.com.libcat.ferris.edu/MonoDisp.aspx?monoID=fandc-hcp1943&quick=159351%7c5&search=159351%7c5&isstemmed=True.
d. Mitchell AA, Van Bennekom CM, Louik C, et al, "A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin," *N Engl J Med*, 1995, 333(2):101-6.
e. iPledge. (2015). Claravis iPledge Program. www.ipledgeprogram.com
f. Graber E, et al "Treatment of Acne Vulgaris," *UptoDate,* November, 10, 2015.

## KERENDIA/FINERENONE

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

**FDA-approved uses**: chronic kidney disease (CKD) with type 2 diabetes

**Available dosage forms**: 10mg, 20mg 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):
  - 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) >25ml/min/1.73m2 AND
    - Urine albumin-to-creatinine ratio >30mg/g AND
    - Serum potassium level <5.0mEq/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 >25ml/min/1.73m2 **AND**
  - Member serum potassium level <5.0mEq/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.

## LARIAM® / MELFLOQUINE

**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 Fibricor)
fenofibric acid (generic for Trilipix®)
Fenoglide®
Lopid®
Lipofen®
Tricor®
Trilipix®

**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: 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
Lovaza®
Nexletol®
Nexlizet®
omega-3 acid ethyl esters capsule (generic for Lovaza)
Vascepa®
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:**

**LOVAZA® (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 ≥500 mg/Dl

**NEXLETOL® (BEMPEDOIC ACID) – PDL CRITERIA DO NOT APPLY**

- Patient is ≥ 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 ≥ 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

**VASCEPA® (ICOSAPENT ETHYL) – PDL CRITERIA DO NOT APPLY**

- Adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia ; **OR**
- Adjunct to maximally tolerated statin therapy in adult patients with elevated triglyceride (TG) levels (≥ 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 >140mmHg systolic or >90mmHg diastolic))

❒ **Duration of Approval**: 1 year

## LIPOTROPICS: PCSK9 INHIBITORS

**Drug Class**: Lipotropics: PCSK9 Inhibitors

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

Praluent®
Repatha®

**REPATHA® *(EVOLOCUMAB)* AND PRALUENT® *(ALIROCUMAB)***
**Initial Request**

- ❒ Diagnosis of atherosclerotic cardiovascular disease (ASCVD), heterozygous familial hypercholesterolemia (HeFH) or homozygous familial hypercholesterolemia (HoFH)
- ❒ Treatment failure with the highest available dose or maximally tolerated dose of high intensity statin (atorvastatin or rosuvastatin) for at least 8 weeks.
- ❒ If intolerant to statins, this must be supported by submitted chart notes/labs.
- ❒ Patient has failed to reach target LDL-C levels (document lab values):
    - ASCVD: LDL-C is < 70 mg/dL
    - HeFH or HoFH: LDL-C is < 100 mg/dL

**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:**
**PRALUENT®**: 2 pens/syringes per 28 days
**REPATHA®:** 140 mg/mL pen/syringe – 2 pens/syringes per 28 days; 420 mg/3.5 mL Pushtronex® – 3.5 mL per 28 days, (for diagnosis of HoFH, Quantity Limit of 7mls per 28 days)

- ❒ **Duration of Approval**: 1 year

## LIPOTROPICS: STATINS

**Drug Class**: Lipotropics: Statins

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

atorvastatin
lovastatin
pravastatin
rosuvastatin
simvastatin

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

amlodipine / atorvastatin
Altoprev®
Caduet®
Crestor®
Ezallor® Sprinkle
ezetimibe/simvastatin
fluvastatin / fluvastatin ER
Lescol XL®
Lipitor®
Livalo®
Vytorin®
Zocor®
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

**EZALLOR® SPRINKLE**

- Patient has difficulty swallowing whole tablets

❒ **Duration of Approval**: 1 year

## LIVTENCITY/ MARIBAVIR

**Drug Class:** CMV Antiviral Agent

**FDA-approved uses**: Livtencity is a cytomegalovirus (CMV) pUL97 kinase inhibitor indicated for the treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

**Available dosage forms**: Tablets 200mg

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

- ❒ **Diagnoses**:
  - Patient 12 years of age and older **and** weighing at least 35 kg; **AND**
  - Patient is a recipient of a hematopoietic stem cell or solid organ transplant; **AND**
  - Active Cytomegalovirus (CMV) infection/disease; **AND**
  - Patient is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet.

- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months

**Other special considerations:**

- If co-administered with carbamazepine arbamazepine: 1,600 mg daily
- If co-administered with phenytoin or phenobarbital: 2,400 mg daily

## 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
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Infection caused by an organism resistant to the preferred macrolide medications
- Therapeutic failure (duration = 3 days) with two preferred medications

**Quantity Limitations:**

| | |
|---|---|
| azithromycin (*Zithromax®*) | 500mg – 3 per fill<br>600mg – 12 per fill<br>1g packet - 2 per fill |
| clarithromycin tabs *(Biaxin®)* | 28 per fill |
| Zithromax® *(azithromycin)* | 500mg – 3 per fill<br>600mg – 12 per fill<br>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)
Gilenya®

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

Aubagio®
Bafiertam™
Copaxone® 40 mg
Extavia®
fingolimod (generic for Gilenya)
glatiramer 20 mg/ml and 40 mg/ml
Glatopa®
Kesimpta®
Mavenclad®
Mayzent®
Plegridy®
Ponvory®
Rebif®/ Rebif Rebidose®
Tecfidera®
Vumerity®
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 one preferred medication
- **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

**BAFIERTAM™ (*MONOMETHYL FUMARATE*), continued**

- 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

**KESIMPTA® *(OFATUMUMAB)***

- 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 Kesimpta will be used as single agent monotherapy
- Attestation that the first injection will be monitored by a healthcare professional

**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 on 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 on two preferred medications

**PLEGRIDY® (*PEGINTERFERON BETA-1A*)**

- Therapeutic failure on 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 on two preferred medications

**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 on two preferred medications

**ZEPOSIA® (*OZANIMOD*)**

- 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 on 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 ≤ 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 ≤ 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**: ≥ 7 years old and > 20 kg
  - **For idiopathic hypersomnia must be > 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]

## NARCOTICS – LONG ACTING

**Drug Class**: Narcotics – Long Acting

**Preferred Agents:** *Clinical Prior Authorization for codeine and tramadol containing products only.*

morphine sulfate ER tablets
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®
buprenorphine film
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®
Nucynta ER®
Oxycontin®
oxycodone ER
oxymorphone ER
tramadol ER capsules
Xtampza ER®

**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

**XTAMPZA ER® (*OXYCODONE*)**

- Diagnosis of severe chronic pain requiring around the clock opioid analgesia; **AND**
- Patient ≥ 18 years old; **AND**
- Alternative treatment options have been ineffective, not tolerated or inadequate for controlling pain

**Quantity Limitations:**

| | |
|---|---|
| Belbuca® *(buprenorphine)* | 60 per 30 days |
| buprenorphine films | 60 per 30 days |
| Oxycontin® ER 10mg *(oxycodone-controlled release tab)* | 180 per 30 days |
| Oxycontin® ER 15mg *(oxycodone-controlled release tab)* | 120 per 30 days |
| Oxycontin® ER 20 mg *(oxycodone-controlled release tab)* | 90 per 30 days |
| Oxycontin® ER 30mg *(oxycodone-controlled release tab)* | 60 per 30 days |
| Oxycontin® ER 40mg *(oxycodone-controlled release tab)* | 45 per 30 days |
| Oxycontin® ER 60 mg *(oxycodone-controlled release tab)* | 30 per 30 days |
| Oxycontin® ER 80mg *(oxycodone-controlled release tab)* | 22 per 30 days |

**Duration of Approval**: 6 months for Zohydro® ER; 1 year for all other medications

**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*.

- Does the patient have documented "current" cancer-related pain?
- Does the patient have pain related to sickle cell disease?
- Is the patient in hospice or palliative care?
- 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
    - Opioid Oral MME conversion factor table can be found under the following resources:
      - https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
      - https://www.hhs.gov/guidance/document/opioid-oral-morphine-milligram-equivalent-mme-conversion-factors-0
  - 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

# Prior Authorization (PA) Request
# Chronic Opioid Management with High Morphine Milligram Equivalents (MME)

**General Instructions:**
Michigan Medicaid recognizes that certain patients will require chronic opioid use at doses higher than the CDC recommendation. In an effort to improve opioid prescribing practices to the Michigan Medicaid population, requests for chronic high dose opioids must be submitted with documentation that supports a chronic pain (pain lasting longer than three months) diagnosis that requires continued use of opioid medications. It is important that all practitioners follow best practices for prescribing chronic opioids. NOTE: A taper to reduce high MME is not always clinically appropriate.

**Best Practices for Opioid Prescribing:**

- **Multifaceted approach** to pain management which includes**:**
  - Assess patient's opioid abuse/addiction potential utilizing a validated risk assessment tool. (Multiple validated tools such as the Opioid Risk Tool (ORT) are available and any template is acceptable.)
  - Use of non-opioid pharmacologic treatments
  - Use of adjuvant, non-pharmacologic therapies such weight loss, physical therapy (PT), occupational therapy (OT), and behavioral therapy.
- **MAPS report** before every controlled substance prescription
- **Toxicology screens (urine or blood) at appropriate intervals**
- **Comprehensive Treatment Plan** with:
  - Discussion of possibility of tapering from high dose opioids (optimize opioids at the lowest dose for pain management while maximizing patient's ability to function)
  - Explanation of risks and benefits of long-term opioid use
  - Pain agreement that includes an informed consent, signed by patient
- Recording any **Overdose History** (prescription or illicit drugs) and the outcome
- Making **Narcan® (naloxone)** opioid overdose recovery medication available to all chronic opioid patients along with instructions on how and when to use.
  - Naloxone covered for all Michigan Medicaid beneficiaries without a prior authorization
  - Prescriptions obtained from practitioner directly or under the State of Michigan Naloxone Standing order at a participating pharmacy
  - Information about Michigan's Standing Order is available online at either www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79678---,00.html or www.michigan.gov/documents/mdhhs/Standing_Order_571880_7.pdf
- The SUPPORT for Patients and Communities Act requires state Medicaid programs to monitor concurrent prescribing of opioids and other drugs when prescribed at the same time, such as benzodiazepines.
  - Information about the CMS guidance to promote proper use of prescription opioids is available at https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf

**Prescribers must attest to the following best practices and provide supportive clinical documentation in some cases:**

- Current **History and Physical with explanation of medical necessity of high MME**
- **Medication List** complete with *all* current opioid and non-opioid medications
- Identification of the total daily MME of all combined opioid medications and when high MME therapy was initiated
- *Pregnant* **patients** on opioids are considered high-risk patients and need to be followed by an OB/GYN whose name must be submitted with request

**References:** K. Kroenke, MD, et al. Challenges with Implementing the Centers for Disease Control and Prevention Opioid Guideline: A Consensus Panel Report. Pain Medicine, 20(4), 2019;724-735, January 2019 https://academic.oup.com/painmedicine/article/20/4/724/5301726All information addressed on this form must be provided for consideration of approval.
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**Criteria for continuation of therapy**:

- ❒ Documentation Requirements:
  - The patient must continue to meet high MME criteria
  - Documentation of taper plan or rationale why taper is not appropriate is required

## NARCOTICS – SHORT AND INTERMEDIATE ACTING

**Drug Class**: Narcotics – 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*

Actiq®
Apadaz®
benzhydrocodone /acetaminophen
butorphanol
codeine / acetaminophen /caffeine /butalbital
codeine / aspirin /caffeine /butalbital
Dilaudid® all forms
fentanyl citrate buccal
Fentora®
Fioricet w/ Codeine®
hydrocodone/ ibuprofen
hydromorphone suppository
levorphanol
Lortab®
meperidine tablets, solution
Nucynta®
oxycodone capsule
oxycodone tabs (20mg, 30mg)
oxycodone oral conc soln
oxycodone oral syringe
oxymorphone
pentazocine/naloxone
Percocet®
Roxicodone®
Seglentis®
tramadol oral solution (generic Qdolo Soln)
Ultracet
Ultram

**Preferred Agent PA Criteria:**

- ≥ 12 years of age (for codeine and tramadol containing products only) **AND**

***SHORT ACTING NARCOTIC 7-DAY LIMIT***

Claims submitted for short acting narcotics 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 NARCOTIC 7-DAY LIMIT***

Claims submitted for short acting narcotics 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®, ACTIQ®, FENTORA®)**

- 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 narcotics must be maximally optimized.
- No concomitant use of other inducers of cytochrome P450
- No concomitant use of other inhibitors of cytochrome P450

**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:**

| | |
|---|---|
| ACTIQ | 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 |
| FENTORA – all strengths | 120 every 24 days |

**Quantity Limitations: continued**

| | |
|---|---|
| HYDROMORPHONE HCL 1 MG/ML ORAL CONC | 120ml per 30 days |
| HYDROMORPHONE HCL 2MG TAB | 180 per 30 days |
| HYDROMORPHONE HCL 4MG TAB | 165 per 30 days |
| HYDROMORPHONE HCL 8MG TAB | 84 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 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 |
| SEGLENTIS 56 MG - 44 MG TAB | 120 per 30 days |
| TRAMADOL SOLUTION 25MG/5ML (QDOLO) | 80 per day (400mg) |

**Duration of Approval**: 14 days for Adapaz®; 1 year for all other medications

**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*.

- Does the patient have documented "current" cancer-related pain?
- Does the patient have pain related to sickle cell disease?
- Is the patient in hospice or palliative care?
- 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
    - Opioid Oral MME conversion factor table can be found under the following resources:
      - https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf
      - https://www.hhs.gov/guidance/document/opioid-oral-morphine-milligram-equivalent-mme-conversion-factors-0
  - 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

# Prior Authorization (PA) Request
# Chronic Opioid Management with High Morphine Milligram Equivalents (MME)

**General Instructions:**
Michigan Medicaid recognizes that certain patients will require chronic opioid use at doses higher than the CDC recommendation. In an effort to improve opioid prescribing practices to the Michigan Medicaid population, requests for chronic high dose opioids must be submitted with documentation that supports a chronic pain (pain lasting longer than three months) diagnosis that requires continued use of opioid medications. It is important that all practitioners follow best practices for prescribing chronic opioids. NOTE: A taper to reduce high MME is not always clinically appropriate.

**Best Practices for Opioid Prescribing:**

- **Multifaceted approach** to pain management which includes**:**
  - Assess patient's opioid abuse/addiction potential utilizing a validated risk assessment tool. (Multiple validated tools such as the Opioid Risk Tool (ORT) are available and any template is acceptable.)
  - Use of non-opioid pharmacologic treatments
  - Use of adjuvant, non-pharmacologic therapies such weight loss, physical therapy (PT), occupational therapy (OT), and behavioral therapy.
- **MAPS report** before every controlled substance prescription
- **Toxicology screens (urine or blood) at appropriate intervals**
- **Comprehensive Treatment Plan** with:
  - Discussion of possibility of tapering from high dose opioids (optimize opioids at the lowest dose for pain management while maximizing patient's ability to function)
  - Explanation of risks and benefits of long-term opioid use
  - Pain agreement that includes an informed consent, signed by patient
- Recording any **Overdose History** (prescription or illicit drugs) and the outcome
- Making **Narcan® (naloxone)** opioid overdose recovery medication available to all chronic opioid patients along with instructions on how and when to use.
  - Naloxone covered for all Michigan Medicaid beneficiaries without a prior authorization
  - Prescriptions obtained from practitioner directly or under the State of Michigan Naloxone Standing order at a participating pharmacy
  - Information about Michigan's Standing Order is available online at either www.michigan.gov/mdhhs/0,5885,7-339-71550_2941_4871_79678---,00.html or www.michigan.gov/documents/mdhhs/Standing_Order_571880_7.pdf
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**Prescribers must attest to the following best practices and provide supportive clinical documentation in some cases:**

- Current **History and Physical with explanation of medical necessity of high MME**
- **Medication List** complete with *all* current opioid and non-opioid medications
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**Criteria for continuation of therapy**:

- ❒ Documentation Requirements:
  - The patient must continue to meet high MME criteria
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## NARCOTICS – TRANSDERMAL

**Drug Class**: Narcotics – 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
- Contraindication or drug to drug interaction with the preferred medication
- History of unacceptable side effects
- Therapeutic failure of one week with the preferred medication

**Quantity Limitations:**

| | |
|---|---|
| Butrans® *(buprenorphine patch)* | 6 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)

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- **Additional documentation:**
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# Prior Authorization (PA) Request
# Chronic Opioid Management with High Morphine Milligram Equivalents (MME)

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- ❒ Documentation Requirements:
  - The patient must continue to meet high MME criteria
  - Documentation of taper plan or rationale why taper is not appropriate is required

## NASAL ANTIHISTAMINES

**Drug Class**: Nasal Antihistamines

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

azelastine (generic for Astepro and Astelin)

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

azelastine/fluticasone spray
Dymista®
olopatadine
Patanase Nasal®

**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 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
Flonase OTC®
flunisolide
fluticasone (OTC)
mometasone
Nasonex®
Omnaris®
Qnasl®
Ticanase®
triamcinolone
Xhance®
Zetonna®

**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 a one-month trial with a preferred medication
- **See additional medication-specific criteria below:**

**XHANCE® (FLUTICASONE)**

- Diagnosis of nasal polyps
- 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)
Lyrica®, Lyrica CR® capsule (*Carve Out)
Neurontin® capsule, tablet, solution (*Carve Out)
Pregabalin capsule, solution (*Carve Out)
Savella® tablet

**GABAPENTIN DOSAGE LIMIT** (*Carve Out)

- Maximum daily dosage limit = 3600 mg across all strengths
- Length of authorization: determined by MDHHS

**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 |
| Savella® (milnacipran) all strengths | 2 per day |

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

Gralise® tablet
Horizant® tablet

**Non-Preferred Agent PA Criteria:**

**GRALISE® (GABAPENTIN)**

- Diagnosis of postherpetic neuralgia, neuropathy, diabetic neuropathy or chronic pain.
- Dosage limit = 1800 mg/day

**HORIZANT® (GABAPENTIN ENACARBIL)**

- Diagnosis of restless leg syndrome; AND
- Therapeutic failure on a one-month trial of pramipexole (Mirapex®), ropinirole (Requip®) or levodopa/carbidopa (Sinemet®): **OR**
- Diagnosis of postherpetic neuralgia (PHN)
- Dosage limit = 1200 mg/day

**Duration of Approval**: 1 year unless otherwise specified

***Carved Out- Bill Fee-For-Service Medicaid**
**(See MPPL @ michigan.magellanrx.com for coverage details)**

## 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®

**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 of one month each with two preferred NSAIDS
- See additional medication-specific criteria below:

**CELEBREX® *(CELECOXIB)***

- Therapeutic failure of a 30-day trial with two or more preferred NSAIDs and the preferred agent in the COX II Inhibitor class

**Quantity Limitations:**
Celebrex® *(celecoxib)* capsules – 2 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
meloxicam tablet
nabumetone
naproxen (generic for Naprosyn®)
sulindac

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

Arthrotec®
Daypro®
diclofenac 2% solution pump
diclofenac epolamine 1.3% patch
diclofenac ER
diclofenac-misoprostol
diclofenac potassium
diflunisal
Duexis®
EC-naproxen
etodolac / etodolac ER
Feldene®
fenoprofen
Flector Patch®
Flurbiprofen
ibuprofen-famotidine
indomethacin ext release
ketorolac nasal spray (generic for Sprix)
ketoprofen ext release
ketoprofen immediate release
Licart Patch®
Lofena®
meclofenamate sodium
mefenamic acid
meloxicam capsule
Mobic®
Nalfon®
Naprelan CR®
naproxen (generic for Anaprox)
naproxen delayed release
naproxen/esomeprazole (generic for Vimovo)
naproxen suspension
oxaprozin
Pennsaid®
piroxicam
Relafen DS®
tolmetin sodium
Vimovo®

**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:**

**LICART® (*DICLOFENAC EPOLAMINE PATCHES*)**

- Length of authorization – 2 months

**SPRIX® (*KETOROLAC TROMETHAMINE*)**

- Contraindication to oral dosage forms (i.e., inability to swallow)
- Length of authorization – 30 days.

**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:**

| | |
|---|---|
| Flector Patch® *(diclofenac transdermal patch)* | 2 per day |
| Toradol® *(ketorolac)* tablets | 21 per fill |
| Licart® *(diclofenac epolamine)* | 15 patches (1 package) per 30 days |

**Duration of Approval**: For the duration of the prescription up to 1 year, unless otherwise noted in Medication-Specific Information

## OPHTHALMIC ANTI-INFLAMMATORY/IMMUNOMODULATOR

**Drug Class**: Ophthalmic Anti-Inflammatory/Immunomodulator

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

Restasis®
Xiidra®

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

Cequa®
cyclosporine (generic Restasis®)
Eysuvis®
Tyrvaya®
Verkazia®

**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
- **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

**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

**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 |
| Tyrvaya | 8.4ml (2 bottles) per 30 days |
| Verkazia | 120 single-dose vials 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
Zaditor®

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

Alrex®
bepotastine
Bepreve®
epinastine
Lastacaft®
Pataday®
Patanol®
Pazeo®
Zerviate®

**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 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
ofloxacin
Vigamox®

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

Besivance®
Ciloxan®
gatifloxacin
levofloxacin
Moxeza®
moxifloxacin (generic for Moxeza®)
moxifloxacin (generic for Vigamox®)
Ocuflox®
Zymaxid®

**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*

Azasite® 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 drops

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

Alocril® drops
Alomide® 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 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
Bromsite®
Ilevro®
ketorolac LS
Nevanac®
Prolensa®

**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
- Medical necessity of lower strength dosages for post-operative pain relief
- Therapeutic failure with a trial with one preferred medication

**Duration of Approval**: 1 year

# ORAL HYPOGLYCEMICS – 2ND 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*

Amaryl®
Glucotrol XL®
Glynase®

**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*

Glumetza®
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*

glyburide / metformin
Invokamet®
Janumet®/Janumet XR®
Jentadueto®
Synjardy®
Xigduo®

**QUANTITY LIMITS:**
Janumet® (sitagliptin / metformin) - 2 tabs per day

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

Actoplus Met®
alogliptin/metformin
alogliptin/pioglitazone
Duetact®
glipizide / metformin
Glyxambi®
Invokamet XR®
Jentadueto XR®
Kazano®
Kombiglyze XR®
Oseni®
pioglitazone/glimepride
pioglitazone/metformin
Qtern®
repaglinide/metformin
Segluromet®
Steglujan®
Synjardy XR®
Trijardy XR

**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 – DPP4 INHIBITORS

**Drug Class**: Oral Hypoglycemics – DPP4 Inhibitors

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

Januvia®
Tradjenta® tablets

**QUANTITY LIMITS**

| | |
|---|---|
| Januvia® (sitagliptin phosphate) | 100mg/day max daily dose limit; qty limit of 1 tab - any strength - per day] |

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

alogliptin tablets
Nesina® tablets
Onglyza® 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
- Therapeutic failure with a one-month trial with two preferred medications within the same class

❒ **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® tablets
Invokana® tablets
Jardiance® tablets

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

Steglatro® 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
- 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

## 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®
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*

calcitonin

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

Forteo®
Miacalcin®
Tymlos®

**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:

**MIACALCIN® (CALCITONIN)**

- Diagnosis of Paget's disease of bone, adjunctive therapy for hypercalcemia or postmenopausal osteoporosis.

**FORTEO® (TERIPARATIDE) – PDL CRITERIA DOES NOT APPLY**

- 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

**TYMLOS® (ABALOPARATIDE) – PDL CRITERIA DOES NOT APPLY**

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures

❒ **Duration of Approval**: 1 year

# 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 QUINOLONES

**Drug Class**: Otic Quinolones

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

Ciprodex®
ofloxacin otic

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

ciprofloxacin otic
ciprofloxacin-dexamethasone
Cipro HC®
Otovel®

**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 (duration = 3 days) with one preferred medication

**Duration of Approval**: 30 days for Otovel®; 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 *(Zyvox®)* | 28 per fill |
| Sivextro® (tedizolid) | 14 per fill |
| Zyvox® tabs *(linezolid)* | 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**: 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 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**: 4 years 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

**Contraindications/Exclusions/Discontinuation**: continued

- 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:**

CREON®, ZENPEP

- Cystic fibrosis or chronic pancreatic insufficiency.

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

Pancreaze®
Pertzye®
Viokace®

**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 trial of one preferred agent
- See additional medication-specific criteria below:

PANCREAZE®, PERTYZE®, VIOKACE®

- Must meet both PDL (trial on preferred medication) and clinical criteria

❒ **Duration of Approval**: 1 year

# PHOSPODIESTERASE-4 (PDE-4) INHIBITORS

**Drug Class**: Phospodiesterase-4 (PDE-4) Inhibitors

**Preferred Agents:**

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

Daliresp®
roflumilast

**Non-Preferred Agent PA Criteria:**

**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*

Brilinta®
clopidogrel
prasugrel

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

aspirin/dipyridamole
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

## PRETOMANID (FOR CONCURRENT USE WITH BEDAQUILINE & LINEZOLID)

**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)
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: If needed, 1 month intervals
- ❒ **Prescriber Specialty**: Infectious disease specialist or pulmonologist, or consultation with
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient is concomitantly taking bedaquiline and linezolid (with a medical necessity PA approval as needed)
    - Bedaquiline
      - Enter approval for
        - Weeks 1 to 2: 400mg once daily
        - Weeks 3 to 24: 200mg 3 times weekly
  - Baseline complete blood counts and electrocardiogram should be obtained
- ❒ **Quantity**: 1/day for 26 weeks (Dosing can be extended, if needed, on a case by case basis)
- ❒ **Age**: > 18 years
- ❒ **Route of Administration**: Oral
- ❒ **Place of Service**: Directly observed therapy (DOT)

**Criteria for continuation of therapy**:

- ❒ Documentation Requirements: Ongoing labs and ECG should be documented.
- ❒ Patient must continue to meet the above criteria; **AND**
- ❒ Patient has demonstrated clinical improvement in response to treatment; **AND**
- ❒ Patient has not developed any contraindications or other exclusions to its continued use.

**Contraindications/Exclusions/Discontinuation**:

Pretomanid is *not* indicated for patients with the following:

- Drug-sensitive (DS) tuberculosis
- Latent infection due to *Mycobacterium tuberculosis*
- Extra-pulmonary infection due to *M. tuberculosis*
- MDR-TB that is not treatment-intolerant or nonresponsive to standard therapy

The safety and effectiveness of pretomanid have not been established for its use in combination with drugs other than bedaquiline and linezolid as part of the recommended dosing regimen.

**Other special considerations:**

- Patients should understand the need for compliance with the full course of treatment.
- The combination regimen should be administered by directly observed therapy (DOT).
- If the regimen is interrupted due to adverse effects follow package insert recommendations for missed dosing.

# PROGESTATIONAL AGENTS

**Drug Class**: Progestational Agents

**Preferred Agents:** *Clinical Prior Authorization for generic Makena IM product only.*

medroxyprogesterone (oral)
progesterone (oral)
norethindrone (oral)
hydroxyprogesterone caproate (IM, generic Delalutin)
hydroxyprogesterone caproate (IM, generic Makena)

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

Aygestin® (oral)
Crinone® (vaginal)
progesterone (intramuscular)
Prometrium® (oral)
Provera® (oral)
Makena Auto-Injector® (subcutaneous)

Preferred Agent Criteria

- Confirmation of diagnosis
- **See additional medication-specific criteria below:**

**Hydroxyprogesterone caproate (generic Makena)**

- Indicated for risk of preterm labor/miscarriage to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth
- Approved for a maximum of 21 weeks per pregnancy
- This physician-administered drug can only be covered under the pharmacy benefit when billed and administered by Home Infusion agency or LTC

**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 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

**MAKENA®** ***(auto-injector)***

- Indicated for risk of preterm labor/miscarriage to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth
- Approved for a maximum of 21 weeks per pregnancy
- This physician-administered drug can only be covered under the pharmacy benefit when billed and administered by Home Infusion agency or LTC

**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® tabs, susp

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

Aciphex® tabs
Dexilant® caps
dexlansoprazole caps
esomeprazole magnesium capsules, susp pkts
esomeprazole magnesium OTC caps
lansoprazole caps, ODT
lansoprazole OTC caps
Nexium® capsules
omeprazole OTC caps, tabs, ODT
omeprazole/sodium bicarbonate (Zegerid RX formulation) caps, susp pkts
pantoprazole suspension
Prevacid caps, solutabs
Prilosec® susp
Rabeprazole tabs
Zegerid® caps, susp pkts

**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*

Alyq®
ambrisentan (generic for Letairis)
Opsumit®
Revatio® suspension
sildenafil tablets (generic for Revatio®)
tadalafil (generic for Adcirca)
Tracleer® tablets
Tyvaso®, Tyvaso DPI®
Uptravi®
Ventavis®

**Clinical PA Criteria:**

- Diagnosis of pulmonary hypertension
- Must be prescribed by a cardiologist or pulmonologist

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

Adcirca®
Adempas®
bosentan tablets (generic for Tracleer)
Letairis®
Orenitram ER®
Revatio® tablets
sildenafil suspension (generic for Revatio)
Tracleer® suspension

**Non-Preferred Agent PA Criteria:**

- Diagnosis of pulmonary hypertension
- Must be prescribed by a cardiologist or pulmonologist
- 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

## 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 ≥ 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® (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® (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
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Infection is caused by an organism that is resistant to the NO PA REQUIRED quinolone medications
- Trial/failure (duration = 3 days) of any two preferred quinolone medications
- Antibiotic therapy initiated in hospital

**Quantity Limitations:**

| | |
|---|---|
| Cipro® tabs (ciprofloxacin) | 42 per fill |
| ciprofloxacin (Cipro®) | 42 per fill |
| levofloxacin tabs (Levaquin®) | 500mg - 14 per fill<br>750mg - 28 per fill |
| moxifloxacin (Avelox®) | 14 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**:

- 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:** 3 months
- **Continuation of Therapy:** 6 months

**Prescriber Specialty:** Nephrologist or Endocrinologist or oncologist by parathyroid carcinoma

**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, failure, intolerance, or contraindication 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)
- **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.

# SKELETAL MUSCLE RELAXANTS

**Drug Class**: Skeletal Muscle Relaxants

**Preferred Agents:** *No Prior Authorization required (except baclofen solution)*

baclofen tablets, solution
cyclobenzaprine
methocarbamol
orphenadrine citrate
tizanidine tablets

**BACLOFEN ORAL SOLUTION (*OZOBAX*)**

- Allow if patient has swallowing difficulties

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

Amrix®
cyclobenzaprine ER
chlorzoxazone
Dantrium®
dantrolene sodium
Fexmid®
Fleqsuvy®
Lorzone®
Lyvispah®
metaxalone
Norgesic Forte®
Skelaxin®
tizanidine capsules
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**

**Duration of Approval**: 1 year

## 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-coporeal 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):
  - 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

# 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 – HIGH POTENCY

**Drug Class**: Topical Steroids – High Potency

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

betamethasone dipropionate cream, lotion, ointment
betamethasone valerate cream
betamethasone valerate ointment
betamethasone valerate lotion
triamcinolone acetonide cream
triamcinolone acetonide ointment
triamcinolone acetonide lotion

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

amcinonide cream
betamethasone diproprionate /propylene glycol cream, gel, lotion, ointment
desoximetasone cream, ointment, gel, and spray
diflorasone diacetate cream and ointment
Diprolene® ointment
fluocinonide cream, ointment, and gel
fluocinonide emollient and solution
Halog® cream and ointment
Kenalog® aerosol
SanadermRx Skin Repair Solution
Sernivo®
Topicort® cream, ointment, gel and spray
Triamcinolone spray
Vanos®

**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
- For **medium potency** and **high potency** medications, trial and failure of 14 days with **both** of the preferred medications
- For **immunocompromised patients**, trial and failure of 14 days with **one** preferred topical steroid

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

## 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
Aqua Glycolic HC®
Capex® shampoo
Derma-smooth – FS ®
Desonide® ointment, cream, lotion
fluocinolone 0.01% oil
Proctocort®
Texacort ®

**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
- For **low potency** and **very high potency** medications, trial and failure of 14 days with **one** of the preferred medications
- For **immunocompromised patients**, trial and failure of 14 days with **one** preferred topical steroid

**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*

fluticasone propionate cream
fluticasone propionate ointment
mometasone furoate ointment
mometasone furoate cream
mometasone furoate solution

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

Beser kit and lotion
betamethasone valerate foam
Cloderm®
clocortolone cream
Elocon ® cream
flurandrenolide cream, lotion, and ointment
fluocinolone acetonide cream, solution
fluticasone propionate lotion
hydrocortisone butyrate cream, lotion, ointment, solution
hydrocortisone valerate cream and ointment
Locoid® cream, lotion, solution
Locoid Lipocream®
Luxiq®
Pandel®
prednicarbate cream and ointment
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
- For **medium potency** and **high potency** medications, trial and failure of 14 days with **both** of the preferred medications
- For **immunocompromised patients**, trial and failure of 14 days with **one** preferred topical steroid

**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 cream
clobetasol propionate ointment
halobetasol propionate cream
halobetasol propionate ointment

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

Bryhali®
clobetasol emollient and lotion
clobetasol propionate foam, gel, spray and shampoo
Clobex® spray and shampoo
Clodan® shampoo and kit
halobetasol propionate (generic for Lexette®)
Impeklo®
Lexette®
Olux®
Olux-E®
Temovate ointment
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
- For **low potency** and **very high potency** medications, trial and failure of 14 days with **one** of the preferred medications
- For **immunocompromised patients**, trial and failure of 14 days with **one** preferred topical steroid

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

## ULCERATIVE COLITIS – ORAL

**Drug Class**: Ulcerative Colitis – Oral

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

Apriso®
Lialda®
sulfasalazine/ sulfasalazine DR

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

Asacol HD®
Azulfidine DR®
Balsalazide
budesonide ER (generic for Uceris)
Colazal®
Delzicol®
Dipentum®
Giazo®
mesalamine (generic for Apriso)
mesalamine (generic for Delzicol)
mesalamine (generic for Lialda)
mesalamine (generic for Pentasa)
Pentasa®
Uceris®

**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 trial with one preferred medication

**Duration of Approval**: 1 year

## URINARY TRACT ANTISPASMODICS

**Drug Class**: Urinary Tract Antispasmodics

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

oxybutynin / oxybutynin ER
solifenacin
Toviaz®

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

darifenacin ER
Detrol®/ Detrol LA®
Ditropan XL®
fesoterodine ER
flavoxate HCL
Gelnique®
Gemtesa®
Myrbetriq®
Oxytrol®
tolterodine/ tolterodine ER
trospium/ 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
- **See additional medication-specific criteria below:**

**GELNIQUE**

- Clinical rationale why preferred agents inappropriate: inability to swallow, etc.

❒ **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)

**ORILISSA® (ELAGOLIX)**

- 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)

**MYFEMBREE® (RELUGOLIX/NORETHINDRONE)**

- Confirmed diagnosis of
  - Uterine leiomyomas (fibroids) with heavy menstrual bleeding; **OR**
  - Moderate to severe pain associated with endometriosis; **AND**
- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **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)

❒ **Duration of Approval**: 1 year (maximum total duration of 24 months)

## VAGINAL ANTIBIOTICS

**Drug Class**: Vaginal Antibiotics

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

Cleocin (clindamycin) Ovules
Clindamycin (generic for Cleocin) 2% cream
metronidazole (generic for Metro-Gel and Vandazole) 0.75% gel
Nuvessa (metronidazole) 1.3% Gel

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

Cleocin (clindamycin) 2% Cream
Clindesse (clindamycin) 2% Cream
Metro-Gel (metronidazole) 0.75% Gel
Vandazole (metronidazole) 0.75% Gel

**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**: 6 months

## VALCYTE® / VALGANCICLOVIR

**Drug Class:** CMV Antiviral Agent – Nucleotide Analogs

**FDA-approved uses:** VALCYTE is a cytomegalovirus (CMV) nucleoside analogue DNA polymerase inhibitor indicated for:

- ❒ **Adult Patients**
  - Treatment of CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS).
  - Prevention of CMV disease in kidney, heart, and kidney-pancreas transplant patients at high risk.
- ❒ **Pediatric Patients**
  - Prevention of CMV disease in kidney and heart transplant patients at high risk.

**Available dosage forms:** Tablets- 450 mg

**Coverage Criteria/Limitations for initial authorization**

- ❒ **Diagnoses:**
  - Cytomegalovirus (CMV) retinitis in HIV-infected patient
  - CMV infection prophylaxis for those at high risk of CMV disease following transplantation of the heart, kidney-pancreas, or kidney
- ❒ **Duration of Approval:**
  - **Initial Approval**: 1 year
  - **Continuation of Therapy**: 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Cytomegalovirus (CMV) retinitis in HIV-infected patient **AND**
    - Documented use in combination with Vitrasert (ganciclovir intraocular implant); **OR**
  - CMV infection prophylaxis for those at high risk of CMV disease following transplantation of the heart, kidney-pancreas, or kidney

**Criteria for continuation of therapy:**

- ❒ **Documentation Requirements (e.g. Labs, Medical Record, Special Studies):**
  - Patient tolerating and responding to treatment

**Contraindications/Exclusions/Discontinuation:**

- Hypersensitivity to valganciclovir or ganciclovir
- patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

## 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**: 6 months

**Prescriber Specialty**: Hepatologist/Gastroenterologist/ Add Infectious disease

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    a. Diagnosis of Chronic Hepatitis B infection with compensated liver disease
    b. HIV testing – mandatory lab report
    c. Failure of Entecavir (geq), at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced
    d. Use is not recommended in those with CrCl < 15mL/minute or if Child-Pugh class B or C
    e. HIV testing: HIV antibody testing should be offered to all HBV infected patients prior to treatment initiation
    f. HBV DNA every three months until undetectable for at least two consecutive visits. We then decrease the frequency to every six months.
    g. Aminotransferases every three months. The frequency can be decreased to every six months in patients with an undetectable HBV DNA or normalized ALT.
    h. HBeAg and antibody to HBeAg (anti-HBe) every six months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, we repeat the HBeAg to confirm the result.
    i. HBsAg should be tested yearly.
    j. Creatinine and phosphate every 6 months.

- ❒ **Quantity**: 30 tablets per 30 days
- ❒ **Age**: 12 and older

**Criteria for continuation of therapy**:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
    a. HBV DNA every three months until undetectable for at least two consecutive visits. We then decrease the frequency to every six months.
    b. Aminotransferases every three months. The frequency can be decreased to every six months in patients with an undetectable HBV DNA or normalized ALT.
    c. HBeAg and antibody to HBeAg (anti-HBe) every six months in patients who are HBeAg-positive to determine if seroconversion has occurred. If HBeAg seroconversion has occurred, we repeat the HBeAg to confirm the result.
    d. HBsAg should be tested yearly.
    e. Creatinine and phosphate every 6 months.

**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 antiretrovial 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 antiretrovial-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 cyclose (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.

## VYNDAMAXAND VYNDAQEL / TAFAMIDIS AND TAFAMIDIS MEGLUMINE

**Drug Class** (ETC_Name): Transthyretin stabilizer

**FDA-approved uses**: Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular (CV) mortality and CV-related hospitalization.

**Available dosage forms**: Vyndaqel (tafamidis meglumine) 20 mg capsules, Vyndamax (tafamidis) 61 mg capsules

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

- ❒ **Diagnoses**: Wild-type or hereditary ATTR-CM
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 1 year
- ❒ **Prescriber Specialty**: Cardiologist **or** a physician in consult with a Cardiologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Documentation of confirmed ATTR-CM diagnosis
  - Attestation – negative history of New York Heart Association (NYHA) Class III heart failure
  - Genetic testing to confirm wild type OR hereditary transthyretin-mediated amyloidosis (ATTR-CM)
  - Medical history of heart failure that includes one of the following: at least 1 prior hospitalization of heart failure OR clinical evidence of heart failure
  - Evidence of cardiac involvement on an echo with increased wall thickness
- ❒ **Quantity**:
  Vyndaqel 20mg capsules: 4/day
  Vyndamax 61mg capsule: 1/day
- ❒ **Age**: 18 and older
- ❒ **Route of Administration**: Oral

**Criteria for continuation of therapy**:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Documentation of clinical benefit through improvement of symptoms

**Contraindications/Exclusions/Discontinuation**:

- Requests will not be approved for members with NYHA Class III heart failure
- Contraindicated in members with previous hypersensitivity to tafamidis or tafamidis meglumine
- Should not be taken concurrently with Onpattro OR Tegsedi

**Other special considerations:**

- Based on animal studies, tafamidis may cause fetal harm when administered during pregnancy, resulting in postnatal mortality, growth retardation, impaired learning.
- Tafamidis meglumine and tafamidis are not substitutable on a milligram-per-milligram basis.
- Pharmacokinetics show no clinically significant differences with mild hepatic impairment (Child-Pugh score of 5-6) when compared to healthy subjects. No dose adjustment is required with moderate impairment (Child-Pugh score of 7-9) since although systemic exposure is decreased in this population, TRR levels are also lower.

## XATMEP® / METHOTREXATE

**Drug Class**: Folate Analog Metabolic Inhibitor

**FDA-approved uses**:
- ❒ Treatment of pediatric patients with acute lymphoblastic leukemia (ALL) as a component of a combination chemotherapy maintenance regimen
- ❒ Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA) who are intolerant of or had an inadequate response to first-line therapy

**Available dosage forms**: 2.5 mg/ml Oral Solution

**Diagnosis:** Treatment of pediatric patients with acute lymphoblastic leukemia (ALL)

**Coverage Criteria/Limitations for initial authorization**

- ❒ **Diagnoses:** Cancer
- ❒ **Duration of Approval:**
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 3-month increments
- ❒ **Prescriber Specialty:** Oncologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Proper diagnosis of an FDA Approved Indication **OR**
  - If request is for a non-FDA Approved indication, the request must be for a "medically accepted indication" as noted in the following Compendia:
    - American Hospital Formulary Drug Service (AHFS-DI)
    - NCCN Drugs and Biologic Compendium/ NCCN Guidelines
      - Categories 1, 2a, and 2b will be accepted. (See Table 1 for explanation of Categories)
    - Micromedex DrugDex
    - Clinical Pharmacology
  - Member must be under the care of an Oncologist
  - Documentation of dose and dates of all previous therapy and the resulting outcomes
  - Documentation that the proper succession of the therapies has been tried and failed (i.e. intolerance, contraindication, or progression)
  - Chart notes detailing the member's current clinical status
  - Related lab work, test results, or clinical markers supporting the diagnosis and or continuing treatment
- ❒ **Not Approved If:**
  - Patient has any contraindications to the use of any requested ingredients
  - Request is for experimental/investigational use
  - Member is enrolled in a clinical trial
- ❒ **Dosing:**
  - As noted in Package Insert
  - As noted in Above described Compendium

**Diagnosis:** Treatment of pediatric patients with acute lymphoblastic leukemia (ALL), continued

**Criteria for continuation of therapy**

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Current chart notes detailing response and compliance to therapy
  - Documented clinically significant improvements in the disease state, and stability on the medication

**Contraindications/Exclusions/Discontinuation:**

- Hypersensitivity to the requested agent or any component of the formulation
- Member at risk through drug-drug interactions of contraindications noted in the package insert
- Patient is noncompliant with medical or pharmacologic therapy
- No demonstrable clinically significant improvement in condition has occulted after initiation of drug therapy

**References:**


- National Comprehensive Cancer Network® (NCCN), "Clinical Practice Guidelines in Oncology™: Available at http://www.nccn.org


| NCCN Categories of Evidence and Consensus |
|---|
| **Category 1:** Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate. |
| **Category 2A:** Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate. |
| **Category 2B:** Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate. |
| **Category 3:** Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| **All recommendations are category 2A unless otherwise noted.** |

**Table 1: NCCN Categories of Evidence and Consensus.**

**Diagnosis:** Management of pediatric patients with active polyarticular juvenile idiopathic arthritis (pJIA)

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

- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must try or have a documented reason that they cannot tolerate oral tablets

**Criteria for continuation of therapy**:

- ❒ Requires a positive response to therapy
- ❒ Patient continues to be unable to tolerate oral tablets