ACE INHIBITORS

Drug Class: ACE Inhibitors

Preferred Agents: *No Prior Authorization required*

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

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
Monopril® / Monopril HCT®
perindopril
Qbrelis®
quinapril / quinapril HCT
trandolapril
Vasotec® / Vaseretic®
Zestril® / Zestoretic®

Non-Preferred Agent PA Criteria:

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

EPANED® *(ENALAPRIL SOLUTION)*

- 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*

clonidine
clonidine ER
clonidine transdermal
guanfacine
methyldopa
Nexiclon XR®

Non-Preferred Agents: *Prior Authorization Criteria below*

methyldopa / HCTZ

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ALZHEIMER'S DEMENTIA

Drug Class: Alzheimer's Dementia

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

AMPYRA® / DALFAMPRIDINE

Drug Class: Multiple Sclerosis Agent – Potassium Channel Blocker

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

Available dosage forms: 10 mg Extended-Release Tablet

Coverage Criteria/Limitations for initial authorization

- ❒ **Diagnoses:** Documented diagnosis of multiple sclerosis with impaired walking ability
- ❒ **Duration of Approval:**
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 1 year
- ❒ **Prescriber Specialty:** Prescribed by a neurologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must not be wheelchair-bound
  - Patient must not have a history of seizures
  - Patient must not have moderate to severe renal impairment (Crcl < 50 ml/min)
  - Patient must be on disease modifying therapy for MS/confirmed diagnosis of MS
  - Documentation of significant and continuous walking impairment that impairs ability to complete normal activities of daily living (such as meal preparation, household chores, etc.) attributable to ambulation or functional status despite optimal treatment for Multiple Sclerosis
  - And, Baseline 25-ft walking test between 8 and 45 seconds
    OR
  - Member is ambulatory***** AND has an Expanded Disability Status Scale (EDSS)****** score **greater than or equal to 4.5 but less than 7**
    **Does not require the use of a wheelchair (bilateral assistance is acceptable, such as a brace, cane, or crutch, as long as the patient can walk 20 meters without resting)*

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

Criteria for continuation of therapy

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

- Member currently meets ALL initial coverage criteria confirmed by documentation
- Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history
- Functional impairment resolved as a result of increased speed of ambulation resulting in the member being able to complete instrumental activities of daily living (such as meal preparation, household chores, etc.)
  AND
- Improvement of at least 20% in timed walking speed as documented by the T25FW (timed 25-foot walk) from pre-treatment baseline:

Contraindications/Exclusions/Discontinuation:

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

AMYLIN ANALOGS

Drug Class Amylin Analogs

Preferred Agents: *No Prior Authorization required*

SymlinPen®

ANDROGENIC AGENTS (TOPICAL)

Drug Class: Androgenic Agents (topical)

Preferred Agents: *Clinical Prior Authorization below*

testosterone gel pump (generic for Androgel)

Clinical PA Criteria:

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Androgel® packet and gel pump
Fortesta®
Natesto
Testim®
testosterone
Vogelxo®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ANGIOTENSIN II-RECEPTOR NEPRILYSIN INHIBITORS (ARNIS)

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

Preferred Agents: *Clinical Prior Authorization below*

sacubitril-valsartan

Non-Preferred Agents: *Prior Authorization Criteria below*

Entresto® Sprinkles
Entresto® Tablets

Non-Preferred Agent PA Criteria:

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

ENTRESTO® *(SACUBITRIL-VALSARTAN)* SPRINKLES

- Allow PDL bypass if patient is unable to swallow tablets
- Quantity Limit: 60 capsules per 30 days

ENTRESTO® *(SACUBITRIL-VALSARTAN)* TABLETS

- Quantity Limit: 60 tablets per 30 days

Duration of Approval: 1 year

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

ANTICHOLINERGIC AGENTS – LONG ACTING

Drug Class: Anticholinergic Agents – Long Acting

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ANTIBIOTICS – INHALED

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ANTICOAGULANTS

Drug Class: Anticoagulants

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Arixtra®
fondaparinux
Fragmin® syringes and vials
Lovenox®
Pradaxa®
Pradaxa Oral Pellets®
rivaroxaban
Savaysa®

Non-Preferred Agent PA Criteria:

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

PRADAXA ORAL PELLETS® (*DAGABITRAN)*

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

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

ANTIEMETICS

D Drug Class: Antiemetics

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

AKYNZEO

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

QUANTITY LIMITS

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

❒ **Duration of Approval**: 1 year

ANTIFUNGALS – ORAL

Drug Class : Antifungals – Oral

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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**
- Attestation that the provider has confirmed a negative pregnancy test or that the patient is not of childbearing potential
- Quantity Limit: Treatment = 4 tablets, Maintenance = 24 tablets
- Length of approval: Treatment = one time, Maintenance = 6 months

CRESEMBA®

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

NOXAFIL® *(POSACONAZOLE)* 300 MG SUSPENSION PACKETS

- Maximum patient age = 17 years

VFEND®

- Aspergillosis – no trial/failure required

SPORANOX®

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

VIVJOA®

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

QUANTITY LIMITS

Brexafemme® tablets	Treatment = 4 tablets, Maintenance = 24 tablets
fluconazole 150 mg tabs *(Diflucan®)*	4 per fill
*terbinafine (*Lamisil®*)*	84 per fill
Sporanox® *(itraconazole) – brand & generic*	100 mg – 120 per 30 days 250 mg kit – 34 per fill 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
econazole nitrate
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
clotrimazole RX solution
Ertaczo®
Extina®
Jublia ®
ketoconazole foam
Ketodan®
Loprox®
Lotrimin AF®
luliconazole
Luzu®
miconazole/zinc oxide/petrolatum
Micotrin AC®
Mycozyl AC®
Naftin®
naftifine
oxiconazole
Oxistat®
tavaborole
Vusion®

Non-Preferred Agent PA Criteria:

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

CICLOPIROX SHAMPOO

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

JUBLIA® *(EFINACONAZOLE)*

- Diagnosis of toenail onychomycosis; and patient age 6 years or older; and trial and failure on ciclopirox or allergy to ciclopirox

TAVABOROLE

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

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

- Maximum patient age = 16 years

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

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
trandolapril / verapamil tablet

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ANTIHYPERTENSIVE COMBINATIONS: ARB

Drug Class : Antihypertensive Combinations: ARB

Preferred Agents: *No Prior Authorization required*

amlodipine/olmesartan
amlodipine/valsartan
amlodipine/valsartan/HCTZ

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ANTIHYPERURICEMIC AGENTS

Drug Class : Antihyperuricemic Agents

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

COLCRYS® (COLCHICINE) TABLETS

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

GLOPERBA® (COLCHICINE) ORAL SOLUTION

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

❒ **Duration of Approval**: 1 year

ANTIMIGRAINE AGENTS, ACUTE TREATMENT - TRIPTANS

Drug Class: Antimigraine Agents, Acute Treatment - Triptans

Preferred Agents: *No Prior Authorization required*

rizatriptan tab and ODT
sumatriptan tablets, injection, nasal spray

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

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

❒ **Duration of Approval**: 6 months

ANTIMIGRAINE AGENTS, ACUTE TREATMENT - OTHER

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

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

Nurtec ODT®
Ubrelvy®

Clinical PA Criteria for Acute Migraines:

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

NURTEC ODT® (RIMEGEPANT) – Quantity Limit: 54 tablets per 90 days
UBRELVY® (*UBROGEPANT*) – Quantity Limit: 16 tablets per 30 days

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

Elyxyb®
Reyvow®
Zavzpret®

Non-Preferred Agent PA Criteria:

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

ELYXYB® (*CELECOXIB*) – Quantity Limit: 14 doses (67.2 ml) per 30 days
REYVOW® (*LASMIDITAN*) – Quantity Limit: 8 tablets per 30 days
ZAVZPRET® (*ZAVEGEPANT*) – Quantity Limit: 8 nasal spray devices per 30 days

❒ **Duration of Approval**: 1 year

ANTIMIGRAINE AGENTS, PREVENTIVE TREATMENT

Drug Class: Antimigraine Agents, Preventive Treatment

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

Aimovig®
Ajovy®
Emgality®
Nurtec ODT®
Qulipta®

Clinical PA Criteria for Migraine Prevention:

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

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

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

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

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

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

ANTI-OBESITY/WEIGHT LOSS AGENTS

Drug Class: Anti-Obesity/Weight Loss Agents

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

benzphetamine (only available as generic); C-III

diethylpropion (only available as generic); C-IV

orlistat products:
orlistat
Xenical (orlistat)

phendimetrazine (only available as generic); C-III

phentermine products:
Adipex-P (phentermine); C-IV
Lomaira (phentermine); C-IV
phentermine; C-IV
phentermine/topiramate (only available as generic); C-IV

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

Initial

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

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

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

Renewal

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

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

liraglutide (generic for Saxenda) [GLP1]
Saxenda® (liraglutide) [GLP1]
Wegovy (semaglutide) [GLP1]
Zepbound® (tirzepatide) [GLP1]

Non-Preferred (GLP1s only) PA Criteria:

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

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

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

Renewal

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

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

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

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

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

QUANTITY LIMITS

Saxenda/liraglutide 18 mg/3 mL pens	15 mL (5 pens) per 30 days
Wegovy (semaglutide) 0.25 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 0.50 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 1 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Wegovy (semaglutide) 1.7 mg/0.75 mL pens	3 mL (4 pens) per 28 days
Wegovy (semaglutide) 2.4 mg/0.75 mL pens	3 mL (4 pens) per 28 days
Xenical (orlistat) 120 mg capsules	90 caps per 30 days
Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 12.5 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Zepbound (tirzepatide) 15 mg/0.5 mL pens	2 mL (4 pens) per 28 days

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

ANTIPARKINSON'S AGENTS – DOPAMINE AGONISTS

Drug Class: AntiParkinson's Agents – Dopamine Agonists

Preferred Agents: *No Prior Authorization required*

pramipexole
ropinirole

Non-Preferred Agents: *Prior Authorization Criteria below*

bromocriptine
Mirapex ER®
Neupro®
Onapgo (apomorphine) cartridge
Parlodel®
pramiprexole ER
ropinirole ER

Non-Preferred Agent PA Criteria:

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

NEUPRO® *(ROTIGOTINE)*

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

Onapgo (apomorphine) cartridge

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

❒ **Duration of Approval**: 1 year

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
entacapone
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 ER (generic for Rytary)
carbidopa/levodopa/entacapone tablet
Crexont®
Dhivy®
Duopa®
Gocovri®
Inbrija®
Lodosyn®
Nourianz®
Ongentys®
Rytary ER®
selegiline capsule, tablet
Sinemet®
Tasmar®
tolcapone
trihexyphenidyl elixir (*Carve Out)
Vyalev®
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

CREXONT® (*CARBIDOPA/LEVODOPA*)

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

GOCOVRI® (*AMANTADINE EXTENDED-RELEASE*)

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

INBRIJA® (*LEVODOPA INHALATION*)

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

ONGENTYS® *(OPICAPONE)*

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

RYTARY ER® (*CARBIDOPA/LEVODOPA ER*)

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

VYALEV® *(FOSLEVODOPA AND FOSCARBIDOPA)*

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

XADAGO® (*SAFINAMIDE*)

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

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

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

ANTIPSORIATIC - TOPICAL VITAMIN D ANALOGS

Drug Class: Dermatological – Antipsoriatics

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

Available dosage forms:

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

Coverage Criteria/Limitations for initial authorization

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

Criteria for continuation of therapy:

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

Contraindications/Exclusions/Discontinuation:

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

ANTIVIRALS – COVID-19

Drug Class Antivirals – COVID-19

Preferred Agents: *No Prior Authorization required*

Paxlovid®

ANTIVIRALS – HERPES

Drug Class: Antivirals – Herpes

Preferred Agents: *No Prior Authorization required*

acyclovir tablets, capsules, suspension
famciclovir
valacyclovir

Non-Preferred Agents: *Prior Authorization Criteria below*

Valtrex®
Zovirax®

Non-Preferred Agent PA Criteria:

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

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

ANTIVIRALS – INFLUENZA

Drug Class: Antivirals – Influenza

Preferred Agents: *No Prior Authorization required*

oseltamivir
Relenza®
rimantadine

Non-Preferred Agents: *Prior Authorization Criteria below*

Flumadine®
Tamiflu®
Xofluza®

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

Tamiflu® and solution *(oseltamivir) – brand & generic*	Capsules – 14 per fill 12 mg/mL solution – 50 mL per fill 6 mg/mL – 120 mL per fill

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

ANTIVIRALS – TOPICAL

Drug Class: Antivirals – Topical

Preferred Agents: *No Prior Authorization required*

acyclovir cream
acyclovir ointment
Denavir®

Non-Preferred Agents: *Prior Authorization Criteria below*

penciclovir (generic for Denavir)
Xerese®
Zovirax® cream
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, XR 6mg, Titration XR (12-18-24), XR 12mg, XR 18mg, XR 24mg, XR 30mg, XR 36mg, XR 42mg, XR 48mg

Coverage Criteria/Limitations for initial authorization:

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

Criteria for continuation of therapy:

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

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)
umeclidinium/vilanterol (DPI)

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

BETA ADRENERGIC AND CORTICOSTEROID INHALER COMBINATIONS

Drug Class: Beta Adrenergic and Corticosteroid Inhaler Combinations

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

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

MAXIMUM AGE LIMITS

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

❒ **Duration of Approval**: 1 year

BETA ADRENERGIC / ANTICHOLINERGIC / CORTICOSTEROID INHALER COMBINATIONS

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

Preferred Agents: *No Prior Authorization required*

Trelegy Ellipta

Non-Preferred Agents: *Prior Authorization Criteria below*

Breztri Aerosphere

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

BETA ADRENERGICS – LONG ACTING

Drug Class: Beta Adrenergics – Long Acting

Preferred Agents: *No Prior Authorization required*

Serevent® (DPI)

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

BROVANA® (ARFORMOTEROL) NEBULIZER SOLUTION

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

PERFOROMIST® (FORMOTEROL) NEBULIZER SOLUTION

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

STRIVERDI RESPIMAT® (OLODATEROL) INHALER

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

❒ **Duration of Approval**: 1 year

BETA ADRENERGICS – SHORT ACTING

Drug Class: Beta Adrenergics – Short Acting

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

Airsupra (albuterol/budesonide)	6 inhalers per 90 days

❒ **Duration of Approval**: 1 year

BETA BLOCKERS

Drug Class: Beta Blockers

Preferred Agents: *No Prior Authorization required*

atenolol
atenolol / chlorthalidone
bisoprolol fumarate
bisoprolol fumarate HCT
carvedilol
Hemangeol oral solution®
labetalol
metoprolol / metoprolol XL
metoprolol succinate
metoprolol tartrate
nadolol
nebivolol
propranolol / propranolol LA
sotalol / sotalol AF

Non-Preferred Agents: *Prior Authorization Criteria below*

acebutolol
Betapace® / Betapace AF®
betaxolol
Bystolic®
carvedilol ER
Inderal LA®/ Inderal XL®
Innopran XL®
Kapspargo®
Lopressor®
metoprolol HCT
pindolol
propranolol HCT
Sotylize®
Tenormin®/ Tenoretic®
timolol maleate
Toprol XL®

Non-Preferred Agent PA Criteria:

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

HEMANGEOL (*PROPRANOLOL*)

- Maximum age of 1 year

❒ **Duration of Approval**: 1 year

BEYFORTUS/ NIRSEVIMAB-ALIP

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

Drug Class Antiviral Monoclonal Antibodies:

FDA-approved uses: Prevention of RSV lower respiratory tract disease in:
- Neonates and infants born during or entering their first RSV season.
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

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

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

BILE SALTS

Drug Class: Bile Salts

Preferred Agents: *No Prior Authorization required*

ursodiol capsules (generic for Actigall)
ursodiol tablets

Non-Preferred Agents: *Prior Authorization Criteria below*

Reltone®
Urso Forte®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

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

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

Preferred Agents: *No Prior Authorization required*

dutasteride
finasteride 5mg (generic for Proscar®)

Non-Preferred Agents: *Prior Authorization Criteria below*

Avodart®
dutasteride/tamsulosin
Proscar®

Non-Preferred Agent PA Criteria:

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

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

BPH AGENTS – ALPHA BLOCKERS

Drug Class: BPH Agents – Alpha Blockers

Preferred Agents: *No Prior Authorization required*

Alfuzosin tablet
Doxazosin tablet
Prazosin capsule
Tamsulosin capsule
Terazosin capsule

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

Tezruly (terazosin) oral solution:

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

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

BRONCHITOL® / MANNITOL

Drug Class: Mucolytic agent

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

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

Coverage Criteria/Limitations for initial authorization:

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

Criteria for continuation of therapy:

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

Contraindications/Exclusions/Discontinuation:

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

Other special considerations:

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

CALCIUM CHANNEL BLOCKERS - DIHYDROPYRIDINE

Drug Class: Calcium Channel Blockers - Dihydropyridine

Preferred Agents: *No Prior Authorization required*

amlodipine besylate
nifedipine / nifedipine SA
Norliqva®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

KATERZIA® SUSPENSION *(AMLODIPINE)*

- Patient age of 6 years or greater
- 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*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

CAMZYOS / MAVACAMTEN

Drug Class: Cardiac Myosin Inhibitors

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

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

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**:
  - Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (HCM)
- ❒ **Duration of Approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: 1 year
- ❒ **Prescriber Specialty**:
  - Prescribed by a cardiologist; **OR**
  - Prescribed in consultation with a cardiologist: Identify Cardiologist Name & NPI:_____ _____
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Member has a left ventricular ejection fraction (LVEF) of ≥ 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

❖ CEPHALOSPORINS - 2ND GENERATION

Preferred Agents: *No Prior Authorization required*

cefuroxime
cefprozil tablet
cefprozil suspension

Non-Preferred Agents: *Prior Authorization Criteria below*

cefaclor
cefaclor ER

❖ CEPHALOSPORINS - 3RD GENERATION

Preferred Agents: *No Prior Authorization required*

cefdinir capsules, suspension
cefixime capsules

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

cefixime suspension
cefpodoxime tablets
cefpodoxime suspension

Non-Preferred Agent PA Criteria:

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

QUANTITY LIMITS

cefaclor caps *(Ceclor®)*	42 per fill
cefaclor ER tabs *(Ceclor CD®)*	42 per fill
cefadroxil caps/tabs *(Duricef®)*	28 per fill
cefdinir tabs *(Omnicef®)*	28 per fill
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*

Fulphila®
Fylnetra®
Neupogen®

Non-Preferred Agents: *Prior Authorization Criteria below*

Granix®
Leukine®
Neulasta® syringe; Neulasta® Onpro Kit
Nivestym®
Nyvepria®
Releuko®
Stimufend®
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:

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

❒ **Duration of Approval**: 1 year

COMBINATION BENZOYL PEROXIDE AND CLINDAMYCIN

Drug Class: Combination Benzoyl Peroxide and Clindamycin

Preferred Agents: *No Prior Authorization required*

clindamycin / benzoyl peroxide

Non-Preferred Agents: *Prior Authorization Criteria below*

Acanya® gel and pump
Cabtreo®
clindamycin / benzoyl peroxide (generic Onexton)
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

COMBINATION NASAL SPRAYS

Drug Class: Combination Nasal Sprays

Preferred Agents:

Non-Preferred Agents: *Prior Authorization Criteria below*

azelastine/fluticasone spray
Dymista®
Ryaltris®

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

CORLANOR® / IVABRADINE

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

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

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

Coverage Criteria/Limitations for initial authorization:
- ❒ **Diagnoses**: Heart failure
- ❒ **Duration of approval**: 12 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    - Diagnosis of stable symptomatic chronic heart failure (NYHA class II, III or IV) **AND**
    - Left ejection fraction ≤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®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ELMIRON® / PENTOSAN POLYSULFATE SODIUM

Drug Class: Urinary tract analgesic agents

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

Available dosage forms: 100mg Capsules

Coverage Criteria/Limitations for initial authorization

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

Criteria for continuation of Therapy

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

Contraindications/Exclusions/Discontinuation:

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

ENDARI / L-GLUTAMINE

Drug Class: Sickle Cell Anemia Agents (N1H)

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

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

Coverage Criteria/Limitations for initial authorization:

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

Contraindications/Exclusions/Discontinuation:

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

ENSPRYNG/ SATRALIZUMAB-MWGE

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

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

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

Coverage Criteria/Limitations for initial authorization:

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

Criteria for continuation of therapy:

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

Contraindications/Exclusions/Discontinuation:

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

Other special considerations:

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

ENTOCORT EC® / BUDESONIDE EC

Drug Class: Crohn disease - Oral

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

Available dosage forms: 3mg EC Capsule

Coverage Criteria/Limitations for initial authorization:

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

EOHILIA / BUDESONIDE

Drug Class : Corticosteroid

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

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

Coverage Criteria/Limitations for authorization:

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

Contraindications/Exclusions/Discontinuation:

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

EPINEPHRINE SELF-ADMINISTERED

Drug Class: Epinephrine Self-Administered

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Auvi-Q®
Neffy®

Non-Preferred Agent PA Criteria:

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

NEFFY® (*EPINEPHRINE*)

- Patient weighs at least 30kg

QUANTITY LIMITS

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

❒ **Duration of Approval**: 1 year

EXSERVAN FILM, TIGLUTIK SUSPENSION / RILUZOLE

Drug Class: ALS Agent - 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

GASTROINTESTINAL ANTIBIOTICS

Drug Class: Gastrointestinal Antibiotics

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

AEMCOLO® (*RIFAMYCIN)*

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

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

- Maximum patient age = 17 years

LIKMEZ® (*METRONIDAZOLE)*

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

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

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

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

GI MOTILITY, CHRONIC

Drug Class:

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

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

Preferred Agents:

Linzess®
lubiprostone

Non-Preferred Agents: *Prior Authorization Criteria below*

Amitiza®
Motegrity®
prucalopride
Trulance®

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

Preferred Agents:

Linzess®
lubiprostone

Non-Preferred Agents: *Prior Authorization Criteria below*

Amitiza®
Ibsrela®
Trulance®

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

Preferred Agents: *Clinical Prior Authorization below*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

alosetron
Lotronex®
Viberzi®

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

Preferred Agents:

lubiprostone

Non-Preferred Agents: *Prior Authorization Criteria below*

Amitiza®
Relistor®
Symproic®
Movantik®

PA Criteria:

Non-Preferred Agents

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

Medication-Specific Criteria

AMITIZA® *(LUBIPROSTONE)*

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

IBSRELA® *(TENAPANOR)*

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

LINZESS® *(LINACLOTIDE)*

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

LOTRONEX® (*ALOSETRON*)

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

MOTEGRITY® (*PRUCALOPRIDE*)

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

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 0.1%
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 (generic for Betimol®)
timolol maleate (generic for Istalol®)
timolol ocudose (generic for Timoptic Ocudose®)
Timoptic®/ Timoptic Ocudose®
Timoptic XE®

❖ GLAUCOMA – CARBONIC ANHYDRASE INHIBITORS

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ GLAUCOMA – COMBINATION ALPHA-2 ADRENERGIC-BETA BLOCKER

Preferred Agents: *No Prior Authorization required*

Combigan®

Non-Preferred Agents: *Prior Authorization Criteria below*

brimonidine-timolol

❖ GLAUCOMA – PROSTAGLANDIN ANALOGUES

Preferred Agents: *No Prior Authorization required*

latanoprost

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ GLAUCOMA – RHO KINASE INHIBITORS

Preferred Agents: *No Prior Authorization required*

Rhopressa®
Rocklatan®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

GLP1S FOR CARDIOVASCULAR RISK REDUCTION

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

Preferred Agents:

Non-Preferred Agents: *Clinical Prior Authorization below*

Wegovy® (semaglutide)

Clinical PA Criteria:

Initial

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

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

Renewal

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

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

QUANTITY LIMITS

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

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

GLP1s FOR MASH

Drug Class: GLP1s for MASH

Preferred Agents:

Non-Preferred Agents: *Clinical Prior Authorization below*

Wegovy® (semaglutide)

Clinical PA Criteria:

Initial

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

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

Renewal

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

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

QUANTITY LIMITS

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

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

GLP1S FOR OBSTRUCTIVE SLEEP APNEA

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

Preferred Agents: *Clinical Prior Authorization below*

Zepbound® (tirzepatide)

Clinical PA Criteria:

Initial

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

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

Renewal

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

QUANTITY LIMITS

Zepbound (tirzepatide) 2.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 7.5 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 10 mg/0.5 mL pens/vials	2 mL (4 pens/vials) per 28 days
Zepbound (tirzepatide) 12.5 mg/0.5 mL pens	2 mL (4 pens) per 28 days
Zepbound (tirzepatide) 15 mg/0.5 mL pens	2 mL (4 pens) per 28 days

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

GLUCAGON AGENTS

Drug Class: Glucagon Agents

Preferred Agents: *No Prior Authorization required*

Baqsimi®
Zegalogue®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

Quantity Limitations:

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

❒ **Duration of Approval**: 1 year

GROWTH HORMONES

Drug Class: Growth Hormones

Preferred Agents: *Clinical Prior Authorization below*

Genotropin®
Norditropin®
Norditropin Flexpro®

Clinical PA Criteria:

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

REQUIRED TESTING INFORMATION:

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

Clinical PA Criteria, continued

- Pediatric patients - bone x-ray report is required ***unless*** the prescriber is a (pediatric) endocrinologist
- Adolescent patients (13 to 19 years of age)– bone x-ray report is required UNLESS the prescriber is a (pediatric) endocrinologist; the requester must also note whether or not the epiphyseal growth plates have closed.
- Adult patients – bone x-ray report is **NOT** required.

- **Papilledema:**
  - Provider is aware of the risk of intracranial hypertension and the role of fundoscopic examination to assess and monitor for papilledema.
- For Idiopathic Short Stature, individual medical record and necessity review will be required.
- Requests that do not meet clinical criteria will require further review and must include the patient's diagnosis including ICD-10, if available. Growth charts should be provided, if available, at time of review (ensure that the correct chart is being submitted based on the patient's age – i.e., 0–3 vs 2–20) in addition to documentation of small for gestational age at birth, if appropriate.

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

NGENLA® *(SOMATROGON-GHLA)*

- Maximum patient age = 16 years

SOGROYA® *(SOMAPACITANB-BECO)*

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

❒ **Duration of Approval**: 1 year

H. PYLORI TREATMENT

Drug Class: H. pylori Treatment

Preferred Agents: *No Prior Authorization required*

Pylera®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

HEMATOPOIETIC AGENTS

Drug Class: Hematopoietic Agents

Preferred Agents: *Clinical Prior Authorization below*

Aranesp®
Epogen®
Retacrit®

Non-Preferred Agents: *Prior Authorization Criteria below*

Jesduvroq®
Procrit®
Vafseo

Non-Preferred Agent PA Criteria:

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

CHRONIC KIDNEY DISEASE STAGE 3, STAGE 4 [CRF - CHRONIC RENAL FAILURE] AND STAGE 5 [ESRD END STAGE RENAL DISEASE] (EPOGEN®, 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®, Aranesp®** 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

JESDUVROQ® (*DAPRODUSTAT*)

Initial

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

Renewal

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

VAFSEO® *(VADADUSTAT)*

Initial

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

Renewal

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

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

HYFTOR / SIROLIMUS

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

FDA-approved uses: Indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients ≥ 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

Drug Class:

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

Biologic Immunomodulators:

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

❖ AGENTS TO TREAT ASTHMA

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®
Fasenra® pen
Xolair® syringes, autoinjectors

Clinical PA Criteria for Asthma Indications:

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

DUPIXENT® *(DUPILUMAB)*:

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

FASENRA® *(BENRALIZUMAB)*:

- **Patient must have severe asthma; AND**
  - Eosinophil blood count of ≥ 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

XOLAIR® *(OMALIZUMAB)*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Nucala® syringe, auto-injector
Tezspire® pen

Non-Preferred Agent PA Criteria:

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

NUCALA® *(MEPOLIZUMAB):*

- **Patient must have severe asthma; AND**
  - Eosinophil blood count of ≥ 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; **AND**
  - For Nucala 40mg/0.4 ml, patient age must be ≤ 11 years of age

TEZSPIRE® *(TEZEPELUMAB-EKKO*)

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT ATOPIC DERMATITIS

Preferred Agents: *Clinical Prior Authorization below*

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

Clinical PA Criteria For Atopic Dermatitis Indications For Each Agent

- **Diagnosis of atopic dermatitis**
  - **Dupixent®**: moderate to severe for ages ≥ 6 months
  - **Elidel®**: mild to moderate for ages ≥ 2 years
  - **Eucrisa®:** mild to moderate for ages ≥ 3 months
  - **Tacrolimus** 0.03%: moderate to severe for ages ≥ 2 years
  - **Tacrolimus** 0.1%: moderate to severe for ages ≥ 16 years

Non-Preferred Agents: *Prior Authorization Criteria below*

Cibinqo®
Ebglyss®
Nemluvio®
Opzelura®
Rinvoq®

❖ AGENTS TO TREAT ATOPIC DERMATITIS, continued

Non-Preferred Agent PA Criteria:

- **Diagnosis of atopic dermatitis**
- Allergy to the preferred medication**; OR**
- Contraindication or drug to drug interaction with the preferred medication**; OR**
- History of unacceptable side effects**; OR**
- Therapeutic failure after a one-month trial of one preferred medication
- Additional disease severity and age limits:
  - **Rinvoq®:** moderate to severe for ages ≥ 12 years
- **See additional medication-specific criteria below:**

ADBRY® (*TRALOKINUMAB-LDRM*)

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

CIBINQO® *(ABROCITINIB)*

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

DUPIXENT® (*DUPILUMAB*)

- Note:
  - A 56-day supply will be allowed for patients requiring dosing once every 28 days (every 4 weeks)
  - The pre-filled PEN is for use in adult and pediatric patients aged 2 years and older.
  - The pre-filled SYRINGE is for use in adult and pediatric patients aged 6 months and older.
- **Diagnosis of moderate to severe atopic dermatitis AND**
  - Patient ≥ 6 months old

EBGLYSS® (*LEBRIKIZUMAB-LBKZ*)

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

NEMLUVIO (*NEMOLIZUMAB-ILTO*)

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

Renewal

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

OPZELURA® *(RUXOLITINIB PHOSPHATE)*

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

QUANTITY LIMITS

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

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

❖ AGENTS TO TREAT CHRONIC IDIOPATHIC URTICARIA / CHRONIC SPONTANEOUS URTICARIA

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®
Xolair® syringes, autoinjectors

Clinical PA Criteria for Chronic Idiopathic Urticaria Indications:

DUPIXENT® *(DUPILUMAB)*:

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

XOLAIR® *(OMALIZUMAB)*

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®

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

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

DUPIXENT® *(DUPILIMAB)*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Nucala®

Non-Preferred Agent PA Criteria:

NUCALA® (MEPOLIZUMAB)

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

❒ **Duration of Approval**: 1 year

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

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®
Xolair® syringes, autoinjectors

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

DUPIXENT® *(DUPILUMAB)*:

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

XOLAIR® *(OMALIZUMAB)*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

Non-Preferred Agent PA Criteria:

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

NUCALA (MEPOLIZUMAB)

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT EOSINOPHILIC ESOPHAGITIS (EOE)

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®

Clinical PA Criteria for eosinophilic esophagitis (EoE):

DUPIXENT® *(DUPILUMAB)*:

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

Preferred Agents: *Clinical Prior Authorization below*

Fasenra®

Clinical PA Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA)

FASENRA® *(BENRALIZUMAB)*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

Non-Preferred Agent PA Criteria:

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

NUCALA® *(MEPOLIZUMAB):*

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT HYPEREOSINOPHILIC SYNDROME (HES)

Non-Preferred Agents: *Prior Authorization Criteria below*

Nucala® syringe, auto-injector

Non-Preferred Agent PA Criteria:

NUCALA® *(MEPOLIZUMAB):*

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT IGE-MEDIATED FOOD ALLERGY

Preferred Agents: *Clinical Prior Authorization below*

Xolair

Clinical PA Criteria for IgE-Mediated Food Allergy

XOLAIR® *(OMALIZUMAB)*

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT NONSEGMENTAL VITILIGO

Non-Preferred Agents: *Prior Authorization Criteria below*

Opzelura®

Non-Preferred Agent PA Criteria:

OPZELURA® *(RUXOLITINIB PHOSPHATE)*

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

❒ **Duration of Approval**: 1 year

❖ AGENTS TO TREAT PRURIGO NODULARIS (PN)

Preferred Agents: *Clinical Prior Authorization below*

Dupixent®

Clinical PA Criteria for Prurigo Nodularis (PN):

DUPIXENT® *(DUPILUMAB)*:

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

Non-Preferred Agents: Prior Authorization Criteria below

Nemluvio®

Non-Preferred Agent PA Criteria:

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

NEMLUVIO® (*NEMOLIZUMAB-ILTO):*

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

❒ **Duration of Approval**: 1 year

BIOLOGIC IMMUNOMODULATORS

❖ AGENTS TO TREAT ANKYLOSING SPONDYLITIS

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ AGENTS TO TREAT CROHN'S DISEASE

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

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Abrilada®
adalimumab-aacf (unbranded Idacio) adalimumab-aaty (unbranded Yuflyma)
adalimumab-adaz (unbranded Hyrimoz)adalimumab-fkjp (unbranded Hulio)
adalimumab-ryvk (unbranded Simlandi)
Amjevita®
Cimzia®, Cimzia Kit®
Cyltezo®
Entyvio®
Hadlima®
Hulio®
Hyrimoz®
Idacio®
Imuldosa®
Omvoh®
Otulfi®
Selarsdi®
Rinvoq®
Simlandi®
Skyrizi®
Stelara®
Tremfya®
ustekinumab-aauz (unbranded Otulfi)
ustekinumab-aekn (unbranded Selarsdi)
ustekinumab-ttwe (unbranded Pyzchiva)
Yesintek®
Yuflyma®
Yusimry®
Zymfentra® pen/syringe

❖ AGENTS TO TREAT GIANT CELL ARTERITIS (GCA)

Preferred Agents: *No Prior Authorization required*

Non-Preferred Agents: *Prior Authorization Criteria below*

Actemra®
Rinvoq®
Tyenne®

❖ AGENTS TO TREAT HIDRADENITIS SUPPURATIVA

Preferred Agents: *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)
Cosentyx®
Humira®

Non-Preferred Agents: *Prior Authorization Criteria below*

Abrilada®
adalimumab-aacf (unbranded Idacio)
adalimumab-aaty (unbranded Yuflyma)
adalimumab-adaz (unbranded Hyrimoz)
adalimumab-fkjp (unbranded Hulio)
adalimumab-ryvk (unbranded Simlandi)
Amjevita®
Bimzelx®
Cyltezo®
Hadlima®
Hulio®
Hyrimoz®
Idacio®
Simlandi®
Yuflyma®
Yusimry®

❖ AGENTS TO TREAT JUVENILE IDIOPATHIC ARTHRITIS

Preferred Agents: *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)
Enbrel®
Humira®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Rinvoq®
Rinvoq LQ®
Simlandi®
Simponi ARIA®
Yusimry®
Tyenne®
Xeljanz® tabs, solution
Yuflyma®

❖ AGENTS TO TREAT NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

Preferred Agents: *No Prior Authorization required*

Cosentyx®

❖ AGENTS TO TREAT NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS, continued

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ AGENTS TO TREAT PLAQUE PSORIASIS

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

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Hadlima®
Hulio®
Hyrimoz®
Idacio®
Imuldosa®
Ilumya®
Otezla®/ Otezla XR®
Otulfi®
Selarsdi®
Simlandi®
Skyrizi®
Sotyktu®
Stelara®
Taltz®
Tremfya®
ustekinumab-aauz (unbranded Otulfi)
ustekinumab-aekn (unbranded Selarsdi)
ustekinumab-ttwe (unbranded Pyzchiva)
Yesintek®
Yuflyma®
Yusimry®

❖ AGENTS TO TREAT PSORIATIC ARTHRITIS

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

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Abrilada®
adalimumab-aacf (unbranded Idacio)
adalimumab-aaty (unbranded Yuflyma)
adalimumab-adaz (unbranded Hyrimoz)
adalimumab-fkjp (unbranded Hulio)
adalimumab-ryvk (unbranded Simlandi)
Amjevita®
Bimzelx®
Cimzia®, Cimzia Kit®
Cyltezo®
Hadlima®
Hulio®
Hyrimoz®
Idacio®
Imuldosa®
Orencia® SC
Otezla® / Otezla XR®
Otulfi®
Selarsdi®
Rinvoq®
Rinvoq LQ®
Simlandi®
Simponi®, Simponi ARIA®
Skyrizi®
Stelara®
Taltz®
Tremfya®
ustekinumab-aauz (unbranded Otulfi)
ustekinumab-aekn (unbranded Selarsdi)
ustekinumab-ttwe (unbranded Pyzchiva)

Xeljanz®, Xeljanz XR®
Yesintek®
Yuflyma®
Yusimry®

❖ AGENTS TO TREAT RHEUMATOID ARTHRITIS

Preferred Agents: *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)
Enbrel®
Humira®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ AGENTS TO TREAT RHEUMATOID ARTHRITIS, continued

Hadlima®
Hulio®
Hyrimoz®
Idacio®
Kevzara®
Kineret®
Olumiant®
Yusimry®
Orencia® SC
Rinvoq®
Simlandi®
Simponi®, Simponi ARIA®
Tyenne®
Xeljanz®, Xeljanz XR®
Yuflyma®

❖ AGENTS TO TREAT ULCERATIVE COLITIS

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

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Abrilada®
adalimumab-aacf (unbranded Idacio)
adalimumab-aaty (unbranded Yuflyma)
adalimumab-adaz (unbranded Hyrimoz)
adalimumab-fkjp (unbranded Hulio)
adalimumab-ryvk (unbranded Simlandi)
Amjevita®
Cyltezo®
Entyvio®
Hadlima®
Hulio®
Hyrimoz®
Idacio®
Imuldosa®
Omvoh®
Otulfi®
Selarsdi®
Rinvoq®
Simlandi®
Simponi®
Skyrizi®
Stelara®
Tremfya®
ustekinumab-aauz (unbranded Otulfi)
ustekinumab-aekn (unbranded Selarsdi)
ustekinumab-ttwe (unbranded Pyzchiva)
Velsipity®
Xeljanz®, Xeljanz XR®
Yesintek®
Yuflyma®
Yusimry®
Zeposia®
Zymfentra® pen/syringe

❖ AGENTS TO TREAT UVEITIS

Preferred Agents: *No Prior Authorization required*

adalimumab-adbm (unbranded Cyltezo)
Humira®

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

ABRILADA® *(ADALIMUMAB-AFZB)*

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

ACTEMRA® *(TOCILIZUMAB)*

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

AMJEVITA® *(ADALIMUMAB-ATT0)*

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

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

BIMZELX® (*BIMEKIZUMAB-BKZX)*

- Diagnosis of moderate to severe plaque psoriasis; **OR**
- Diagnosis of active psoriatic arthritis (PsA); **OR**
- Diagnosis of active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation; **OR**
- Diagnosis of active ankylosing spondylitis (AS); **OR**
- Diagnosis of moderate-to-severe hidradenitis suppurativa (HS); **AND**
- Patient must be 18 years or older

CYLTEZO® *(ADALIMIMAB-ADBM)*

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

ENTYVIO® (*VEDOLIZUMAB*)

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

HADLIMA® *(ADALIMUMAB-BWWD)*

- Patient is 2 years of age or older**; AND**
  - Diagnosis of moderate to severe polyarticular juvenile idiopathic arthritis**; OR**
- Patient is 6 years of age or older**; AND**

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

HULIO® *(ADALIMUMAB-FKJP)*

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

HYRIMOZ® *(ADALIMUMAB-ADAZ)*

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

IDACIO® *(ADALIMUMAB-AACF)*

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

- Diagnosis of moderate to severe rheumatoid arthritis**; OR**
- Diagnosis of psoriatic arthritis**; OR**
- Diagnosis of ankylosing spondylitis**; OR**
- Diagnosis of moderate to severe ulcerative colitis**; OR**
- Diagnosis of moderate to severe plaque psoriasis**; OR**
- Diagnosis of moderate to severe hidradenitis suppurativa**; OR**
- Diagnosis of non-infectious intermediate, posterior, or panuveitis

ILUMYA® (*TILDRAKIZUMAB*)

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

IMULDOSA® (*USTEKINUMAB-SRLF*)

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

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

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

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

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

OMVOH

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

OTEZLA® / OTEZLA XR® (*APREMILAST*)

- Patient must be 6 years or older; **AND**
  - Diagnosis of active psoriatic arthritis; OR
  - Diagnosis of plaque psoriasis**; OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of active psoriatic arthritis **; OR**
  - Diagnosis of plaque psoriasis**; OR**
  - Diagnosis of oral ulcers associated with Behcet's Disease**; AND**
- Must be prescribed by or in consultation with a rheumatologist or dermatologist
- OTEZLA is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 20 kg
- OTEZLA XR is indicated for the treatment of adult patients and pediatric patients 6 years of age and older and weighing at least 50 kg

OTULFI® (*USTEKINUMAB-AAUZ*)

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

PYZCHIVA® (*USTEKINUMAB-TTWE*)

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

RINVOQ® (*UPADACITINIB)*

- Patient must be 2 years or older; **AND**
  - Diagnosis of psoriatic arthritis**; OR**
  - Diagnosis of polyarticular juvenile idiopathic arthritis; **OR**
- Patient must be 18 years or older; **AND**
  - Diagnosis of moderate to severe rheumatoid arthritis; **OR**
  - Diagnosis of ankylosing spondylitis**; OR**
  - Diagnosis of non-radiographic axial spondyloarthritis (nr-axSpA**); OR**

- Diagnosis of giant cell arteritis; **OR**
- Diagnosis of moderately to severely active Crohn's disease**; OR**
- Diagnosis of moderately to severely active ulcerative colitis

RINVOQ LQ® (*UPADACITINIB)*

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

SELARSDI® (USTEKINUMAB-AEKN)

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

SIMLANDI® *(ADALIMUMAB-RYVK)*

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

SKYRIZI® (*RISANKIZUMAB*)

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

- Prescribed by or in consultation with a gastroenterologist or rheumatologist

SOTYKTU® *(DEUCRAVACITINIB)*

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

STELARA® *(USTEKINUMAB)*

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

STEQEYMA (*USTEKINUMAB-STBA)*

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

TALTZ® (*IXEKIZUMAB*)

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

TREMFYA® (*GUSELKUMAB)*

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

TYENNE® (*TOCILIZUMAB-AAZG)*

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

UNBRANDED PYZCHIVA® (*USTEKINUMAB-TTWE*)

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

UNBRANDED OTULFI® (*USTEKINUMAB-AAUZ*)

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

VELSIPITY® *(ETRASIMOD ARGININE)*

- Diagnosis of moderately to severely active ulcerative colitis (UC); **AND**
- Patient must be 18 years or older; **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**

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

YESINTEK (*USTEKINUMAB-STBA)*

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

XELJANZ® / XELJANZ XR® / XELJANZ® SOLUTION (*TOFACITINIB*)
Xeljanz tablets and Xeljanz Solution:

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

Xeljanz tablets and Xeljanz XR tablets:

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

YUFLYMA® *(ADALIMUMAB-AATY)*

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

- Diagnosis of psoriatic arthritis**; OR**
- Diagnosis of ankylosing spondylitis**; OR**
- Diagnosis of moderate to severe ulcerative colitis**; OR**
- Diagnosis of moderate to severe plaque psoriasis**; OR**
- Diagnosis of moderate to severe hidradenitis suppurativa**; OR**
- Diagnosis of non-infectious intermediate, posterior, or panuveitis

YUSIMRY® *(ADALIMUMAB-AQVH)*

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

ZEPOSIA® *(OZANIMOD)*

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

ZYMFENTRA® *(INFLIXIMAB-DYYB)*

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

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

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

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

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

TABLE 1 – QUANTITY LIMITS (BIOLOGICS)		5 Pages Total
Drug Name	**Package Size**	**Limitation ***
OTEZLA 30 MG TABLET	1 each	2 each per day
OTEZLA XR INITIATION PK 28 DAY	41 each	41 each (1 kit) per year
OTEZLA XR 75 MG TABLET	1 each	1 each per day
OTULFI 130 MG/26 ML VIAL	1 vial (26 mL)	104 mL per 365 days
OTULFI 45 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 84 days
OTULFI 45 MG/0.5 ML VIAL	0.5 mL	0.5 mL per 84 days
OTULFI 90 MG/ML SYRINGE	1 mL	1 mL per 84 days
PYZCHIVA 130 MG/26 ML VIAL	1 vial (26 mL)	104 mL per 365 days
PYZCHIVA 45 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 84 days
PYZCHIVA 45 MG/0.5 ML VIAL	0.5 mL	0.5 mL per 84 days
PYZCHIVA 90 MG/ML SYRINGE	1 mL	1 mL per 84 days
RINVOQ ER 15 MG TABLET	1 each	1 each per day
RINVOQ ER 30 MG TABLET	1 each	1 each per day
RINVOQ ER 45 MG TABLET	1 each	1 each per day
RINVOQ LQ 1 MG/ML SOLUTION	1 mL	12 mL per day
SELARSDI 130 MG/26 ML VIAL	1 vial (26 mL)	104 mL per 365 days
SELARSDI 45 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 84 days
SELARSDI 45 MG/0.5 ML VIAL	0.5 mL	0.5 mL per 84 days
SELARSDI 90 MG/ML SYRINGE	1 mL	1 mL per 84 days
SIMLANDI(CF) 20 MG/0.2 ML SYRINGE	1 each or 2 each	2 per 28 days
SIMLANDI(CF) 40 MG/0.4 ML AUTOINJECTOR	1 each or 2 each	4 per 28 days
SIMLANDI(CF) 40 MG/0.4 ML SYRINGE	1 each or 2 each	4 per 28 days
SIMLANDI(CF) 80 MG/0.8 ML AUTOINJECTOR	1 each or 2 each	2 per 28 days
SIMLANDI(CF) 80 MG/0.8 ML SYRINGE	1 each or 2 each	2 per 28 days
SIMPONI 100 MG/ML PEN INJECTOR	1 mL	1 mL per 28 days
SIMPONI 100 MG/ML SYRINGE	1 mL	1 mL per 28 days
SIMPONI 50 MG/0.5 ML PEN INJEC	0.5 mL	0.5 mL per 28 days
SIMPONI 50 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 28 days
SKYRIZI 150 MG/ML PEN	1 mL	1 mL per 84 days
SKYRIZI 150 MG/ML SYRINGE	1 mL	1 mL per 84 days
SKYRIZI 180 MG/1.2 ML ON-BODY	1.2 mL	1.2 mL per 56 days
SKYRIZI 360 MG/2.4 ML ON-BODY	2.4 mL	2.4 mL per 56 days
SOTYKTU 6 MG TABLET	1 each	1 each per day
STELARA 130 MG/26 ML VIAL	1 vial (26 mL)	104 mL per 365 days
STELARA 45 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 84 days
STELARA 45 MG/0.5 ML VIAL	0.5 mL	0.5 mL per 84 days
STELARA 90 MG/ML SYRINGE	1 mL	1 mL per 84 days
STEQEYMA 130 MG/26 ML VIAL	1 vial (26 mL)	104 mL per 365 days
STEQEYMA 45 MG/0.5 ML SYRINGE	0.5 mL	0.5 mL per 84 days
STEQEYMA 90 MG/ML SYRINGE	1 mL	1 mL per 84 days
TALTZ 20 MG/0.25 ML SYRINGE	0.25 mL	0.25 mL per 28 days

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

TABLE 1 – QUANTITY LIMITS (BIOLOGICS)		5 Pages Total
Drug Name	**Package Size**	**Limitation ***
ZYMFENTRA 120 MG/ML PEN KIT (2 PACK)	1 each	1 each per 28 days

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

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

INCRETIN MIMETICS AND COMBINATIONS

Drug Class:

- ❒ Incretin Mimetics
- ❒ Incretin Mimetics - Combinations

❖ INCRETIN MIMETICS

Preferred Agents: *Clinical Prior Authorization below*

Byetta®
Ozempic®
Trulicity®
Victoza®

Clinical Preferred Agent PA Criteria:

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Bydureon Bcise®
exenatide
liraglutide
Mounjaro®
Rybelsus®

❖ INCRETIN MIMETICS – COMBINATIONS

Non-Preferred Agents: *Prior Authorization Criteria below*

Soliqua®
Xultophy®

Non-Preferred Agent PA Criteria:

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

SOLIQUA® *(INSULIN GLARGINE/LIXISENATIDE)*

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

XULTOPHY® *(INSULIN DEGLUDEC/LIRAGLUTIDE)*

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

QUANTITY LIMITS

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

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

INGREZZA / VALBENAZINE

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

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

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

Coverage Criteria/Limitations for initial authorization:

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

Criteria for continuation of therapy:

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

INHALED GLUCOCORTICOIDS

Drug Class: Inhaled Glucocorticoids

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Armonair Digihaler
fluticasone prop diskus (Generic Flovent Diskus)
fluticasone ellipta (Generic Arnuity Ellipta)
Pulmicort® 1mg Respules nebulizer solution
Pulmicort® 0.25mg and 0.5mg Respules

Non-Preferred Agent PA Criteria:

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

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

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

QUANTITY LIMITS

Asmanex (mometasone) HFA	3 inhaler per 90 days

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

MAXIMUM AGE LIMITS

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

❒ **Duration of Approval**: 1 year

INSULIN SUPPRESSANTS

Drug Class: Insulin Suppressants

Preferred Agents: *No Prior Authorization required*

Proglycem

Non-Preferred Agents: *Prior Authorization Criteria below*

diazoxide (generic for Proglycem)

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

INSULINS

Drug Class:

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

❖ INSULINS, MIXES

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ INSULINS, BASAL

Preferred Agents: *No Prior Authorization required*

Lantus® pens, vials
Levemir® pens, vials

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ INSULINS, RAPID ACTING

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

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

❖ INSULINS, TRADITIONAL

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Novolin® N vials
Novolin® R vials

Non-Preferred Agent PA Criteria:

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

LYUMJEV™ (*INSULIN LISPRO-AABC*)

- Quantity limit = 90 per fill

MERILOG® (*INSULIN ASPART-SZJJ)*

- Quantity limit = 90 ml per fill

MERILOG SOLOSTAR® (*INSULIN ASPART-SZJJ)*

- Quantity limit = 90 ml per fill

REZVOGLAR® *(INSULIN GLARGINE-AGLR)*

- Quantity limit = 90 per fill

❒ **Duration of Approval**: 1 year

ISOTRETINOIN / CLARAVIS®

ISOTRETINOIN / AMNESTEEM®

ISOTRETINOIN / ZENATANE™

Drug Class: Acne Therapy Systemic - Retinoids & Derivatives

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

Coverage Criteria/Limitations for initial authorization:

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

- ❒ **Age:** 12 years and older
- ❒ **Route of Administration:** Oral

Criteria for second authorization:

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

JYNARQUE/ TOLVAPTAN

Drug Class : Vasopressin V_2-receptor antagonist

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

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

Coverage Criteria/Limitations for initial authorization:

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

Criteria for continuation of therapy:

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

Other special considerations:

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

KERENDIA / FINERENONE

Drug Class: Mineralocorticoid (Aldosterone) Receptor Antagonists

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

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

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: diagnosis of chronic kidney disease (CKD) with type 2 diabetes
- ❒ **Duration of approval**:
  - **Initial authorization**: 1 year
  - **Continuation of Therapy**: 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - 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.

MEFLOQUINE

Drug Class: Antimalarial

FDA-approved uses:

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

Available dosage forms: 250mg Tablets

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

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

Contraindications/Exclusions/Discontinuation:

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

LEUKOTRIENE INHIBITORS

Drug Class: Leukotriene Inhibitors

Preferred Agents: *See Age Criteria for chew tablets below*

montelukast tablets, 4mg chew tabs, 5mg chew tabs

Non-Preferred Agents: *Prior Authorization Criteria below*

Accolate®
montelukast granules
Singulair® tablets, 4mg chew tabs, 5mg chew tabs, granules
zafirlukast
Zileuton ER®
Zyflo®

Non-Preferred Agent PA Criteria:

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

MONTELUKAST (SINGULAIR®)

- clinical rationale why the (swallow) tablet dosage form inappropriate for the following age limits:
  - 4mg chew tabs – prior authorization (PA) required for patients > 5
  - 5mg chew tabs – PA required for patients > 14
  - Granules – PA required for patients > 5; Requests for granules for patients <5 may bypass PDL criteria if the patient is unable to chew or swallow a tablet.

❒ **Duration of Approval**: 1 year

LIDOCAINE 5% PATCH

Drug Class: Dermatological - Topical Local Anesthetic Amides

FDA-approved uses: Post-herpetic neuralgia (PHN)

Available dosage forms: Lidocaine 5% patch

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses:** (any of the following)
  - Post-herpetic neuralgia (PHN)
  - Diabetic neuropathic pain
  - Peripheral polyneuropathy not due to post-herpetic neuralgia, diabetes, or cancer with history of substance use disorder (SUD)
  - SUD related concerns
- ❒ **Duration of Approval:**
  - **Initial Authorization:**
    - PHN: Up to 90 days
    - Neuropathic pain: initially 2 months
    - Pain with SUD related concerns: Up to 6 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **For diabetic neuropathic pain only:** Trial of at least 2 of the following or contraindication to all of the following:
    - Gabapentin
    - tricyclic antidepressant
    - nerve block
    - trigger point injection
    - SNRIs
    - TENS unit
- ❒ **Quantity:** Max 3 patches per day (may be cut to cover areas of most severe pain)

Criteria for continuation of therapy:

- Requires positive response to the use of the patch
- Duration of approval: Up to 12 months

Contraindications/Exclusions/Discontinuation:

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

LIPOTROPICS: FIBRIC ACID DERIVATIVES

Drug Class: Lipotropics: Fibric Acid Derivatives

Preferred Agents: *No Prior Authorization required*

fenofibrate, nanocrystallized (generic for Tricor®)
fenofibric acid capsules (generic for Lofibra® caps)
fenofibrate tablets (generic for Lofibra tablets)
gemfibrozil

Non-Preferred Agents: *Prior Authorization Criteria below*

Antara®
fenofibrate, micronized capsules (generic for Antara)
fenofibrate, nanocrystallized (generic for Triglide®)
fenofibric acid (generic for Fibricor)
fenofibric acid (generic for Trilipix®)
Fenoglide®
Fibricor®
Lopid®
Lipofen®
Tricor®
Trilipix®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

LIPOTROPICS: NIACIN DERIVATIVES

Drug Class: Lipotropics: Niacin Derivatives

Preferred Agents: *No Prior Authorization required*

niacin tablets (OTC)
niacin ER tablets (OTC)
niacin ER capsules (OTC)

Non-Preferred Agents: *Prior Authorization Criteria below*

niacin ER (generic for Niaspan)

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

LIPOTROPICS: NON-STATINS - BILE ACID SEQUESTRANTS

Drug Class: Lipotropics: Non-Statins - Bile Acid Sequestrants

Preferred Agents: *No Prior Authorization required*

cholestyramine/ cholestyramine light
colestipol tablets
Prevalite powder, packets

Non-Preferred Agents: *Prior Authorization Criteria below*

Colestid® tablet
colestipol granules
colesevelam tablet, packet
Questran®/ Questran Light®
Welchol® powder and tablets

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

LIPOTROPICS: OTHERS

Drug Class: Lipotropics: Others

Preferred Agents: *No Prior Authorization required*

ezetimibe

Non-Preferred Agents: *Prior Authorization Criteria below*

icosapent ethyl
Nexletol®
Nexlizet®
omega-3 acid ethyl esters capsule
Zetia®

Non-Preferred Agent PA Criteria:

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

OMEGA-3 ACID ETHYL ESTERS – PDL CRITERIA DO NOT APPLY

- Adjunct to diet to reduce severe triglyceride (TG) levels (hypertriglyceridemia) in adult patients.
- Triglyceride levels ≥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

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
ezetimibe/simvastatin
lovastatin
pravastatin
rosuvastatin
simvastatin

Non-Preferred Agents: *Prior Authorization Criteria below*

amlodipine / atorvastatin
Altoprev®
Atorvaliq®
Caduet®
Crestor®
Ezallor® Sprinkle
fluvastatin / fluvastatin ER
Lescol XL®
Lipitor®
Livalo®
pitavastatin
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
- **See additional medication-specific criteria below:**

ATORVALIQ® *(ATORVASTATIN)*

- Patient cannot swallow whole tablets;
- Quantity Limit: 20 ml per day

EZALLOR® SPRINKLE *(ROSUVASTATIN)*

- Patient cannot swallow whole tablets

❒ **Duration of Approval**: 1 year

LITFULO/ RITLECITINIB

Drug Class: Janus Kinase (JAK) Inhibitors / TEC family kinase inhibitor

FDA-approved uses: Indicated for the treatment of severe alopecia areata in adults and adolescents 12 years and older.

Available dosage forms: 50mg Capsule

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Severe alopecia areata
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 1 year
- ❒ **Prescriber Specialty**: Prescribed by or in consultation with a dermatologist
- ❒ **Documentation Requirements** (e.g., Labs, Medical Record, Special Studies):
  - Severity of Alopecia Tool (SALT) score of ≥50 (range: 0 to 100, with 0 representing no scalp hair loss and 100 complete scalp hair loss); **AND**
  - Current AA episode lasting at least 6 months without spontaneous regrowth; **AND**
  - Documentation of inadequate response to a 3-month trial of at least **one** of the following:
    - intralesional corticosteroid therapy; **OR**
    - prescription topical corticosteroid therapy (e.g., betamethasone dipropionate); **OR**
    - systemic immunomodulator therapy (e.g., corticosteroids, methotrexate, cyclosporine)
- ❒ **Quantity**: 1 capsule per day
- ❒ **Age**: ≥12 years of age

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider documentation of clinical improvement in hair regrowth as indicated by improvement in post-treatment SALT score

Contraindications/Exclusions/Discontinuation:

- Not covered for patients with a diffuse hair loss pattern or other forms of alopecia such as androgenetic alopecia (Hamilton-Norwood classification system grade IV or greater) or chemotherapy-induced hair loss
- Cannot be used in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants (e.g., methotrexate, azathioprine)

MACROLIDES

Drug Class: Macrolides

Preferred Agents: *No Prior Authorization required*

Azithromycin
Clarithromycin
erythromycin ethylsuccinate tablets
erythromycin ethylsuccinate 200mg suspension
Erythrocin®

Non-Preferred Agents: *Prior Authorization Criteria below*

clarithromycin ER
E.E.S.® tablet, suspension
EryPed®
Ery-Tab®
Erythromycin base
erythromycin ethylsuccinate 400mg suspension
Zithromax® tablets, suspension

Non-Preferred Agent PA Criteria

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Infection caused by an organism resistant to the preferred macrolide medications**; OR**
- Therapeutic failure (duration = 3 days) with two preferred medications
- **See additional medication-specific criteria below:**

ZITHROMAX (*AZITHROMYCIN)* 500MG TABLETS

- **Allow up to 10 tablets per fill for Lyme disease**

Quantity Limitations:

azithromycin (*Zithromax®*)	500mg – 5 per fill 600mg – 12 per fill 1g packet - 2 per fill
clarithromycin tabs *(Biaxin®)*	28 per fill
Zithromax® *(azithromycin)*	500mg – 5 per fill 600mg – 12 per fill

	1g packet - 2 per fill

Duration of Approval: Date of service

MARINOL® / DRONABINOL

Drug Class: Antiemetic - Cannabinoids

FDA-approved uses:
- ❒ Appetite stimulation in AIDS patients
- ❒ Chemotherapy-induced nausea and vomiting

Available dosage forms: Capsules: 2.5 mg, 5 mg, 10 mg,

Coverage Criteria/Limitations for initial authorization:
- ❒ **Diagnosis:** ***chemotherapy induced nausea and vomiting***
- ❒ **Duration of Approval**:
  - **Initial Authorization:** duration of the chemotherapy treatment
  - **Continuation of Therapy:** limited time -- determined based on the plan of care developed utilizing the chemotherapeutic agents
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must be receiving chemotherapy and meet the following criteria:
    - Intolerant or refractory to first line agents such as Zofran
    - Patient must be under close supervision during the initial use and during dose adjustments due to its potential for altered mental status
    - The number of pills approved will be limited to the amount necessary for a single cycle of chemotherapy.
  - **For antiemetic purposed**: trial and failure, intolerance, or contraindication to an emetic regimen that includes a serotonin antagonist (ondansetron, granisetron), dexamethasone, promethazine, or prochlorperazine
  - **For cancer:** trial and failure, intolerance, or contraindication to an emetic regimen consistent with NCCN guidelines
- ❒ **Age restrictions:** adults and pediatrics
- ❒ **Prescriber Specialty**: Oncologist

Criteria for continuation of therapy:
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Decreased episodes of nausea and vomiting.

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnosis:** ***appetite stimulation in AIDS patients***
- ❒ **Duration of Approval**:
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must have AIDS with anorexia associated with weight loss
  - Must have trial and failure, intolerance, or contraindication to megestrol
- ❒ **Age restrictions:** adults only
- ❒ **Prescriber Specialty**: Infectious Disease specialist

Criteria for continuation of therapy:

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Response to treatment with the patient stabilizing one's weight.

Contraindication/Exclusion/Discontinuation:

- Hypersensitivity to dronabinol, cannabinoids, sesame oil, or any component of the formulation
- In addition, therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:

- Use cautiously in individuals with the following conditions as they may worsen with use of this product:
  - Seizure
  - Psychiatric disorders
  - Drug Abuse and dependence
  - Cardiovascular disorders.

MEPRON® / ATOVAQUONE

Drug Class: Antiprotozoal Agents - Other

FDA-approved uses: *Pneumocystis jiroveci* pneumonia:

- ❒ **Prophylaxis:** Prevention of *P. jiroveci* pneumonia (PCP) in adults and adolescents 13 years and older who are intolerant to trimethoprim-sulfamethoxazole (TMP-SMZ).
- ❒ **Treatment:**
  Acute oral treatment of mild to moderate PCP in adults and adolescents 13 years and older who are intolerant to trimethoprim-sulfamethoxazole.

Available dosage forms: 750mg/5ml Oral Suspension

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses:** FDA approved uses as listed above
- ❒ **Prescriber Specialty:** Infectious Disease
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Failure or contraindication to TMP-SMZ
- ❒ **Quantity:** 21 day supply
- ❒ **Age:** 13 years or older
- ❒ **Route of Administration:** Oral

Contraindications/Exclusions/Discontinuation:

- Patient is noncompliant with medical or pharmacologic therapy.
- No demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.
- Hypersensitivity to atovaquone or any component of the formulation.

MULTIPLE SCLEROSIS AGENTS

Drug Class: Multiple Sclerosis Agents

Preferred Agents: *No Prior Authorization required*

Avonex®
Betaseron® vial / Betaseron® Kit
Copaxone 20 mg
dimethyl fumarate (generic for Tecfidera)
fingolimod (generic for Gilenya)
Kesimpta®
teriflunomide (generic for Aubagio)

Non-Preferred Agents: *Prior Authorization Criteria below*

Aubagio®
Bafiertam™
Copaxone® 40 mg
cladribine 10 mg (generic for Mavenclad)
glatiramer 20 mg/ml and 40 mg/ml
Gilenya®
Glatopa®
Mavenclad®
Mayzent®
Plegridy®
Ponvory®
Rebif®/ Rebif Rebidose®
Tascenso ODT®
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 two preferred medications
- **See additional medication-specific criteria below:**

BAFIERTAM™ (*MONOMETHYL FUMARATE*)

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Attestation that Bafiertam will be used as single agent monotherapy
- Quantity limit: 120 per 30 days
- Initial length of authorization: 6 months
- Renewal criteria:
  - Attestation of tolerance to maintenance dose.

- Attestation of a CBC, including lymphocyte count, serum aminotransferase, ALP, and total bilirubin levels

MAVENCLAD® (*CLADRIBINE*)

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include relapsing-remitting disease and active secondary progressive disease; **AND**
- Prescribed by or in consultation with a neurologist
- Therapeutic failure of one-month trial of at least two preferred medications

MAYZENT® (*SIPONIMOD*)

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient CYP2C9 variant status has been tested to determine genotyping (required for dosing); **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

PLEGRIDY® (*PEGINTERFERON BETA-1A*)

- Therapeutic failure of one-month trial of at least two preferred medications required.

PONVORY® *(PONESIMOD)*

- Patient age between 18 years and 55 years; **AND**
- Patient has a diagnosis of a relapsing form of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) or active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Prescriber attestation that first-dose monitoring, as clinically indicated, will occur; **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY**: A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Prescriber attestation that ponesimod will NOT be used in combination with anti-neoplastic, immunosuppressive, or immune-modulating therapies, or, if therapy is unavoidable, the patient will be monitored closely for adverse reactions and/or dose modifications; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

TASCENSO ODT® *(FINGOLIMOD)*

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Patient age ≥10 years; **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Patient is unable to use generic fingolimod capsules or brand Gilenya capsules due to swallowing difficulties.

VUMERITY® (*DIROXIMEL FUMARATE*)

- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **AND**
- Therapeutic failure of one-month trial of at least two preferred medications

ZEPOSIA® (*OZANIMOD*)

- Patient is 18 Years of age or older; **AND**
- Diagnosis of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome (CIS), relapsing-remitting disease (RRMS) and active secondary progressive disease (SPMS); **AND**
- Prescribed by or in consultation with a neurologist; **OR**
- Diagnosis of moderately or severely active ulcerative colitis (UC); **AND**
- Prescribed by or in consultation with a gastroenterologist; **AND**
- Patient has obtained a baseline electrocardiogram (ECG); **AND**
- Patient does NOT have an active infection, including clinically important localized infections; **AND**
- Patient has been tested for antibodies to the varicella zoster virus (VZV) or has completed the immunization series for VZV prior to beginning therapy; **AND**
- For patients with a history of uveitis and/or diabetes **ONLY:** A baseline ophthalmic evaluation of the fundus, including the macula, before starting treatment; **AND**
- Prescriber attests that a CBC with lymphocyte count, ALT, AST, and total bilirubin have been obtained for the patient in the past 6 months; **AND**
- For MS, therapeutic failure of one-month trial of at least two preferred MS medications.
- For UC, may bypass PDL criteria.

Quantity Limitations:

AVONEX®	4 per 34 days
BAFIERTAM®	120 per 30 days

Duration of Approval: 1 year

NARCOLEPSY AGENTS
XYREM / SODIUM OXYBATE
XYWAV / CALCIUM, MAGNESIUM, POTASSIUM, SODIUM OXYBATE

Drug Class: Narcolepsy Agents

Agents: *Prior Authorization Criteria below*

Xywav® - Rationale for lower sodium needed for approval of Xywav except when the indication is for idiopathic hypersomnia in adults.
Sodium Oxybate

FDA-approved uses: Excessive daytime sleepiness/cataplexy: Treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy: Idiopathic hypersomnia in adults.

Available dosage forms: Oral solution, 500 mg per mL

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**:
  - Type 1 Narcolepsy (cataplexy in narcolepsy)
  - Type 2 Narcolepsy [narcolepsy without cataplexy; excessive daytime sleepiness (EDS) in narcolepsy]
  - Idiopathic hypersomnia (Xywav only)
- ❒ **Duration of approval:**
  - **Initial authorization**: 3 months
  - **Continuation of Therapy**: for up to 6 months
- ❒ **Prescriber Specialty:** Board-certified Sleep Medicine Specialist, neurologist, pulmonologist, or psychiatrist. Submit consultation notes if applicable.
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies, Pharmacy claims, Physician attestation):
  - Daily excessive daytime sleepiness for at least 3 months (AASM ICSD-3 Criteria)
  - Nocturnal polysomnography (PSG) confirmation
    - Overnight polysomnography to rule out other conditions and confirm adequate sleep before first Multiple Sleep Latency Test (MSLT)
  - Positive MSLT* including:
    - Mean Sleep Latency ≤ 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)

- ❒ **<u>Documentation Requirements</u>** (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 ≥ 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]

NASAL ANTIHISTAMINES

Drug Class: Nasal Antihistamines

Preferred Agents: *No Prior Authorization required*

azelastine

Non-Preferred Agents: *Prior Authorization Criteria below*

olopatadine

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

NASAL CORTICOSTEROIDS

Drug Class: Nasal Corticosteroids

Preferred Agents: *No Prior Authorization required*

fluticasone (Rx)

Non-Preferred Agents: *Prior Authorization Criteria below*

Beconase AQ®
budesonide
flunisolide
fluticasone (OTC)
mometasone spray (RX)
mometasone 24hr (OTC)
Nasonex 24hr (OTC)
Omnaris®
Qnasl®
triamcinolone
Xhance®
Zetonna®

Non-Preferred Agent PA Criteria:

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

XHANCE® (*FLUTICASONE*)

- Diagnosis of chronic rhinosinusitis with or without nasal polyps in adults
- Therapeutic failure with a three-month trial with a preferred medication

Duration of Approval: 1 year

NEUROPATHIC PAIN

Drug Class: Neuropathic Pain

Preferred Agents: *No Prior Authorization required*

Cymbalta® capsule (*Carve Out)
Drizalma Sprinkles® capsule (*Carve Out)
duloxetine (generic for Cymbalta) capsule (*Carve Out)
duloxetine (generic for Irenka) capsule (*Carve Out)
gabapentin capsule, tablet, solution (*Carve Out)
gabapentin ER tablet (generic for Gralise®)
Gabarone® (*Carve Out)
Gralise®
Horizant®
Lyrica®, Lyrica CR® capsule (*Carve Out)
Neurontin® capsule, tablet, solution (*Carve Out)
Pregabalin capsule, solution (*Carve Out)
Savella® tablet

LYRICA (PREGABALIN) DOSAGE LIMIT (*Carve Out)

- Maximum daily dosage limit = 600 mg across all strengths
- Length of authorization: determined by MDHHS

Quantity Limitations:

Lyrica® (pregabalin)	25 mg - 3 per day 50 mg - 3 per day 75 mg – 3 per day 100 mg – 3 per day 150 mg – 3 per day 200 mg – 3 per day 225 mg – 2 per day 300 mg – 2 per day 20 mg/ml – 20 ml per day

Duration of Approval: 1 year unless otherwise specified

***Carved Out- Bill Fee-For-Service Medicaid**
(See MPPL @ mi.primetherapeutics.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 one month each with two preferred NSAIDS (unless clinically contraindicated), including generic celecoxib.

QUANTITY LIMITS

Celebrex 50mg, 100mg, 200mg capsules	2 per day
Celebrex 400mg	2 per day
celecoxib 50mg, 100mg, 200mg capsules	2 per day
celecoxib 400mg	2 per day

Duration of Approval: For the duration of the prescription up to 1 year

NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

Drug Class: Non-Steroidal Anti-Inflammatory Drugs (NSAIDS)

Preferred Agents: *No Prior Authorization required*

diclofenac
diclofenac topical gel 1% (generic Voltaren Gel®)
diclofenac topical gel 1% (OTC)
diclofenac topical solution 1.5%
ibuprofen
indomethacin
ketorolac tablets
meloxicam tablets
nabumetone
naproxen OTC
naproxen (generic for Naprosyn®)
sulindac

Non-Preferred Agents: *Prior Authorization Criteria below*

Arthrotec®
Daypro®
diclofenac ER
diclofenac epolamine 1.3% patch
diclofenac-misoprostol
diclofenac potassium
diclofenac 2% pump (generic Pennsaid)
diflunisal
Dolobid®
dual action pain (OTC -ibuprofen/apap)
EC-naproxen
etodolac / etodolac ER
Feldene®
fenoprofen
flurbiprofen
ibuprofen 300 mg tablet
ibuprofen-famotidine
indomethacin ext release, oral susp
ketoprofen ext release
ketoprofen immediate release
Lofena®
meclofenamate sodium
mefenamic acid
meloxicam capsules
Nalfon®
Naprelan CR®
Naprosyn Suspension®
naproxen (generic for Anaprox)
naproxen delayed release
naproxen/esomeprazole (generic for Vimovo)
naproxen suspension
oxaprozin
Pennsaid®
piroxicam
Relafen DS®
Tolectin®
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:**

ibuprofen 300 mg tablet

- Prescriber will need to justify medical necessity of unique strength
- Length of approval: For the duration of the prescription up to 1 year

VIMOVO® (*NAPROXEN/ESOMEPRAZOLE*) AND DUEXIS® (*IBUPROFEN/FAMOTIDINE*)

- History of or active GI bleed/ulcer OR
- Risk for bleed/ulcer –
- Therapeutic failure with one preferred medication

Quantity Limitations:

diclofenac transdermal patch	2 per day
Toradol® *(ketorolac)* tablets	21 per fill

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

OHTUVAYRE (ENSIFENTRINE)

Drug Class (ETC_Name): Respiratory Phosphodiesterase 3 and 4 (PDE3 and PDE4) Inhibitors

FDA-approved uses: Indicated for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients

Available dosage forms: 3 mg/2.5 mL ampule (nebulizer solution) - 60 ampules per carton

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: moderate to severe chronic obstructive pulmonary disease (COPD)
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 12 months
- ❒ **Prescriber Specialty**: Prescribed by or in consultation with a pulmonologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Spirometry demonstrating FEV1/FVC ratio <0.7; **AND**
  - Post-bronchodilator FEV1 ≥30% and ≤ 80% of predicted normal; **AND**
  - Modified Medical Research Council (mMRC) dyspnea score of ≥ 2 **OR** COPD Assessment Test (CAT) score of ≥ 10; **AND**
  - Patient had inadequate response after a 3-month trial of either a LAMA/LABA dual-maintenance therapy or LAMA/LABA/ICS triple-maintenance therapy; **AND**
  - Patient will continue LAMA/LABA dual therapy or LAMA/LABA/ICS triple therapy in combination with Ohtuvayre unless not tolerated or contraindicated; **AND**
  - Member does not have a diagnosis of asthma; **AND**
  - Prescriber attests Ohtuvayre will not be used in combination with roflumilast
- ❒ **Quantity**: 150 mL (60 ampules) / 30 days
- ❒ **Age**: Patient is 18 years of age or older
- ❒ **Route of Administration**: Nebulized oral inhalation

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Must demonstrate a decrease in symptoms and/or COPD exacerbations vs baseline; **AND**
  - Continue use of dual or triple therapy that includes (LABA/LAMA) in conjunction with Ohtuvayre **AND**
  - Prescriber attests Ohtuvayre will not be used in combination with roflumilast

OPHTHALMIC ANTI-INFLAMMATORY/IMMUNOMODULATOR/DRY EYE

Drug Class: Ophthalmic Anti-Inflammatory/Immunomodulator

Preferred Agents: *No Prior Authorization required*

Restasis® single-use vials
Xiidra®

Non-Preferred Agents: *Prior Authorization Criteria below*

Cequa®
cyclosporine (generic Restasis®)
Eysuvis®
Miebo®
Restasis® multidose vials
Tryptyr® (acoltremon)
Tyrvaya®
Verkazia®
Vevye®

Non-Preferred Agent PA Criteria:

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

EYSUVIS® (*LOTEPREDNOL*):

- For Renewal: Patient has had an examination under magnification (e.g., slit lamp) and evaluation of the intraocular pressure (IOP)
- Renewal length of approval: 2 weeks

MIEBO® *(PERFLUOROHEXYLOCTANE/PF)*

- Patient is 18 years of age or older; **AND**
- **Quantity Limit:** 3.0 mls per 30 days

TRYPTYR® *(ACOLTREMON)*

- Patient is 18 years of age or older; **AND**
- **Quantity Limit:** 60 single dose vials (one vial can be used to dose both eyes) 30 days

VERKAZIA® *(CYCLOSPORINE):* (PDL criteria do not apply)

- Patient is ≥4 years of age; **AND**
- Diagnosis of moderate to severe vernal keratoconjunctivitis; **AND**
- Trial and failure, contraindication, or intolerance to one of the following:

- Topical ophthalmic "dual-action" mast cell stabilizer and antihistamine (e.g., olopatadine, azelastine) **OR**
- Topical ophthalmic mast cell stabilizers (e.g., cromolyn); **AND**

- Prescribed by or in consultation with an ophthalmologist or optometrist.

VEVYE® (*CYCLOSPORINE*)

- Patient is 18 years of age or older; **AND**
- Quantity Limit: 2 ml per 30 days

QUANTITY LIMITS

Restasis (cyclosporine) single-use containers	60 per 30 days
Restasis multi-dose vial	5.5ml (1 vial) per 30 days
Xiidra	60 single-use containers per 30 days
Cequa	60 single-use containers per 30 days
Eysuvis	8.3ml (1 bottle) per 14 days
Miebo	3ml per 30 days
Tryptyr	60 single dose vials (one vial can be used to dose both eyes) 30 days
Tyrvaya	8.4ml (2 bottles) per 30 days
Verkazia	120 single-dose vials per 30 days
Vevye	2ml per 30 days

❒ **Duration of Approval**: 1 year (except Eysuvis – 2 weeks)

OPHTHALMIC ANTIHISTAMINES

Drug Class: Ophthalmic Antihistamines

Preferred Agents: *No Prior Authorization required*

azelastine
ketotifen fumarate (OTC Only)
olopatadine (OTC Only)

Non-Preferred Agents: *Prior Authorization Criteria below*

alcaftadine
Alrex®
bepotastine
Bepreve®
epinastine
Lastacaft®
loteprednol (generic for Alrex)
olopatadine RX
Pataday®
Zaditor®
Zerviate®

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

OPHTHALMIC FLUOROQUINOLONES

Drug Class: Ophthalmic Fluoroquinolones

Preferred Agents: *No Prior Authorization required*

ciprofloxacin
moxifloxacin (generic for Vigamox®)
ofloxacin

Non-Preferred Agents: *Prior Authorization Criteria below*

Besifloxacin (generic for Besivance)
Besivance®
Ciloxan® 0.3% Oint. (G)
gatifloxacin
levofloxacin
moxifloxacin (generic for Moxeza®)
Ocuflox®
Vigamox®

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

OPHTHALMIC MACROLIDES

Drug Class: Ophthalmic Macrolides

Preferred Agents: *No Prior Authorization required*

erythromycin 0.5% eye ointment

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Alomide®

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

OPHTHALMIC NSAIDS

Drug Class: Ophthalmic NSAIDS

Preferred Agents: *No Prior Authorization required*

diclofenac
flurbiprofen
ketorolac

Non-Preferred Agents: *Prior Authorization Criteria below*

Acular®
Acular LS®
Acuvail®
bromfenac
bromfenac (generic for Bromsite®)
bromfenac (generic for Prolensa®)
Bromsite®
Ilevro®
ketorolac LS
Nevanac®
Prolensa®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Medical necessity of lower strength dosages for post-operative pain relief**; OR**
- Therapeutic failure with a trial with one preferred medication

Duration of Approval: 1 year

OPIOIDS – LONG ACTING

Drug Class: Opioids – Long Acting

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

morphine sulfate ER tablets
Oxycontin®
tramadol ER tablets

Preferred Agent PA Criteria:

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Belbuca®
Conzip ER®
Diskets
hydrocodone ER capsules (generic Zohydro ER®)
hydrocodone ER tablets (generic Hysingla ER®)
hydromorphone ER®
Hysingla ER®
Methadone
Methadose tablet dispersible, oral concentrate
morphine sulfate ER caps (generic Avinza®)
morphine sulfate ER caps (generic Kadian®)
MS Contin®
oxycodone ER
oxymorphone ER
tramadol ER capsules

Non-Preferred Agent PA Criteria:

- ≥ 12 years of age (for codeine and tramadol containing products only) **AND**
- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Therapeutic failure of one week with one preferred medication
- **See additional medication-specific criteria below:**

BELBUCA® (*BUPRENORPHINE BUCCAL FILM*)

- Diagnosis of moderate to severe chronic pain requiring around the clock opioid analgesia; **AND**
- Patient ≥ 18 years old

Quantity Limitations:

Belbuca® *(buprenorphine)*	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

*__Note__: High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

Initial High MME Exceptions: If any are "True", no further information is required and member meets the requirements for this section. If all are "False" then proceed to the remaining requirements under *Additional High MME Criteria*.

1. Does the patient have documented "current" cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

Additional High MME Criteria:

- **Provider must attest to all of the following:**
  - Risk assessment has been performed
  - Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
  - MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber's assessment the drugs and doses are safe for the member.
  - Concurrently prescribed drugs have been reconciled and reviewed for safety
  - The following Non-opioid pain interventions have been recommended and/or utilized:
    - Non-opioid medications
    - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
  - A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
  - Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
  - If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).

- **Additional documentation:**
  - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
  - Recent non-opioid medications utilized for pain management or rationale these cannot be used
  - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
  - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
    - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR
    - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

Criteria for Continuation of Therapy:

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

OPIOIDS – SHORT AND INTERMEDIATE ACTING

Drug Class: Opioids – Short and Intermediate Acting

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

codeine
codeine / acetaminophen
Endocet
hydrocodone / acetaminophen
hydromorphone oral tablets
morphine sulfate tablets, solution, suppository
oxycodone tabs (5mg, 10mg, 15mg)
oxycodone oral solution
oxycodone / acetaminophen
tramadol / acetaminophen
tramadol

Non-Preferred Agents: *Prior Authorization Criteria below*

butorphanol
codeine / acetaminophen /caffeine /butalbital
codeine / aspirin /caffeine /butalbital
Dilaudid® all forms
fentanyl citrate buccal
Fioricet w/ Codeine®
hydrocodone/ ibuprofen
hydromorphone suppository
levorphanol
meperidine tablets, solution
Nalocet®
oxycodone capsule
oxycodone tabs (20mg, 30mg)
oxycodone oral conc soln
oxymorphone
pentazocine/naloxone
Percocet®
Prolate®
Roxicodone®
RoxyBond®
Seglentis®
tramadol oral solution (generic Qdolo Soln)

Preferred Agent PA Criteria:

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

SHORT ACTING OPIOID 7-DAY LIMIT

Claims submitted for short acting opioids for more than a 7-day supply for opioid naïve patients (i.e., those with no claim for an opioid medication within the past 180 days) will deny for prior authorization.

Non-Preferred Agent PA Criteria:

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

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

SHORT ACTING OPIOID 7-DAY LIMIT
Claims submitted for short acting opioids for more than a 7-day supply for opioid naïve patients (i.e., those with no claim for an opioid medication within the past 180 days) will deny for prior authorization.

FENTANYL – ORAL (ABSTRAL®)
- Management of breakthrough cancer pain in patients established on immediate release and long-acting opioid therapy.
- Requests for controlled substances must be under the name and ID of the prescribing physician.
- > 18 years of age
- Medication must be prescribed by a physician who is experienced in the use of Schedule II opioids
- Current dosage regimen of the long acting and regularly prescribed immediate release opioids must be maximally optimized.
- No concomitant use of other inducers of cytochrome P450
- No concomitant use of other inhibitors of cytochrome P450

ROXYBOND® *(OXYCODONE)* TABLETS
- PDL criteria may be bypassed to allow coverage if an abuse deterrent formulation is needed

SEGLENTIS (CELECOXIB/TRAMADOL)
- Patient age is 12 years and older; **AND**
- Prescriber attests that Seglentis will not be used for postoperative management in children younger than 18 years of age following tonsillectomy and/or adenoidectomy; **AND**
- Quantity Limit=120 tablets per 30 days

TRAMADOL (QDOLO®) ORAL SOLUTION
- Patient age is 12 years and older; **AND**
- Allow if patient has difficulty swallowing tablets
- Quantity limit = 80 ml per day (400mg/day)

Quantity Limitations:

FENTANYL CITRATE	120 units/30 days for each strength
BUTORPHANOL 10MG/ML NASAL SPRAY	15 mL per 30 days
CODEINE SULFATE 15 MG TAB	180 per 30 days
CODEINE SULFATE 30MG TAB	180 per 30 days
CODEINE SULFATE 60 MG TAB	180 per 30 days
HYDROMORPHONE HCL 1 MG/ML ORAL CONC	120ml per 30 days

Quantity Limitations: continued

HYDROMORPHONE HCL 2MG TAB	180 per 30 days
HYDROMORPHONE HCL 4MG TAB	135 per 30 days

HYDROMORPHONE HCL 8MG TAB	67 per 30 days
MEPERIDINE HCL 50MG TAB	120 per 30 days
MEPERIDINE HCL 50 MG/5ML SOLN	240ml per 30 days
MORPHINE SULFATE 10 MG /5ML SOLN	240ml per 30 days
MORPHINE SULFATE 100 MG/5ML SOLN	120 per 30 days
MORPHINE SULFATE 10 MG/0.5ML ORAL SYR	120 per 30 days
MORPHINE SULFATE 20 MG/ML ORAL SYR	120 per 30 days
MORPHINE SULFATE 15 MG TAB	180 per 30 days
MORPHINE SULFATE 20 MG/5ML SOLN	240ml per 30 days
MORPHINE SULFATE 30 MG TAB	90 per 30 days
OXYCODONE HCL 5 MG CAP	90 per 30 days
OXYCODONE HCL 5MG TAB	90 per 30 days
OXYCODONE HCL 5MG/5ML SOLN	240ml per 30 days
OXYCODONE HCL 20MG/ML SOLN	90ml per 30 days
OXYCODONE HCL 10MG TAB	90 per 30 days
OXYCODONE HCL 15 MG TAB	90 per 30 days
OXYCODONE HCL 20 MG TAB	90 per 30 days
OXYCODONE HCL 30 MG TAB	60 per 30 days
OXYMORPHONE HCL 5MG TAB	120 per 30 days
OXYMORPHONE HCL 10MG TAB	90 per 30 days
ROXYBOND 5MG TAB	90 per 30 days
ROXYBOND 10MG TAB	90 per 30 days
ROXYBOND 15MG TAB	90 per 30 days
ROXYBOND 30MG TAB	60 per 30 days
SEGLENTIS 56 MG - 44 MG TAB	120 per 30 days
TRAMADOL SOLUTION 25MG/5ML (QDOLO)	80 per day (400mg)

Duration of Approval: 1 year

Chronic Opioid Management with High Morphine Milligram Equivalents (MME)

***Note**: High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

Initial High MME Exceptions: If any are "True", no further information is required and member meets the requirements for this section. If all are "False" then proceed to the remaining requirements under *Additional High MME Criteria*.

1. Does the patient have documented "current" cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

Additional High MME Criteria:

- **Provider must attest to all of the following:**
  - Risk assessment has been performed

- Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
- MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber's assessment the drugs and doses are safe for the member.
- Concurrently prescribed drugs have been reconciled and reviewed for safety
- The following Non-opioid pain interventions have been recommended and/or utilized:
  - Non-opioid medications
  - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
- A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
- Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
- If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).

- **Additional documentation:**
  - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
  - Recent non-opioid medications utilized for pain management or rationale these cannot be used
  - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
  - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
    - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR
    - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

Criteria for Continuation of Therapy:

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

OPIOIDS – TRANSDERMAL

Drug Class: Opioids – Transdermal

Preferred Agents: *No Prior Authorization required*

Butrans® patches
fentanyl patches 12, 25, 50, 75, and 100 mcg only (generic only)

Non-Preferred Agents: *Prior Authorization Criteria below*

buprenorphine patches
fentanyl generic patches 37.5 mcg, 62.5 mcg and 87.5 mcg only

Non-Preferred Agent PA Criteria:

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

Quantity Limitations:

Butrans® *(buprenorphine patch)*	4 per 28 days
fentanyl patch (Duragesic®)	10 per fill

Duration of Approval: 1 year

Chronic Opioid Management with High Morphine Milligram Equivalents (MME)
*__Note__: High MME applies to all opioids (i.e. short acting, long, acting, transdermal)

Initial High MME Exceptions: If any are "True", no further information is required and member meets the requirements for this section. If all are "False" then proceed to the remaining requirements under *Additional High MME Criteria*.

1. Does the patient have documented "current" cancer-related pain?
2. Does the patient have pain related to sickle cell disease?
3. Is the patient in hospice or palliative care?
4. Patient resides in a long-term care or other facility that is exempt from reporting to or checking the State Prescription Drug Monitoring Program (i.e. MAPS) (NOTE: upon discharge from long-term care member must meet the additional high MME Criteria below).

Additional High MME Criteria:

- **Provider must attest to all of the following:**
    - Risk assessment has been performed
    - Pain Medication Agreement with informed consent has been reviewed with, completed and signed by the patient
    - MAPS/NarxCare report has been reviewed by prescriber in last 30 days. (Please do not submit the MAPS report.) Concurrently prescribed drugs have been reviewed and that based on prescriber's assessment the drugs and doses are safe for the member.
    - Concurrently prescribed drugs have been reconciled and reviewed for safety
    - The following Non-opioid pain interventions have been recommended and/or utilized:
        - Non-opioid medications
        - Adjuvant therapies such as physical therapy (PT), occupational therapy (OT), behavioral therapies, or weight loss
    - A toxicology screen (urine or blood) from a commercial lab has been performed at appropriate intervals. Results from toxicology screen showed expected results.
    - Patient has been counseled on obtaining and the appropriate utilization of a Narcan (naloxone) kit.
    - If applicable, the patient has been counselled on the potential increased risk of adverse effects when opioids are taken concomitantly with opioid potentiators (e.g. benzodiazepines/sedative hypnotics, stimulants, gabapentinoids, muscle relaxers).
- **Additional documentation:**
    - Current documentation provided outlining pain related history and physical(s) including clinical justification supporting need for exceeding high MME
    - Recent non-opioid medications utilized for pain management or rationale these cannot be used
    - Documentation includes list of all current opioid medications (long and short-acting) and when the regimen was initiated.
    - Duration of current opioid therapy and current daily Morphine Milligram Equivalent
        - There are numerous apps that can be used to calculate the daily MME. Additional information on Calculating Total Daily Dose of Opioids is available at: CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022 | MMWR
        - If patient is currently pregnant, must provide the name and location of the OB/GYN following this high-risk pregnancy

Criteria for Continuation of Therapy:

- Must continue to meet high MME criteria and provide all required documentation
- Documentation of taper plan or rationale why taper is not appropriate

ORAL HYPOGLYCEMICS – 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*

Glucotrol XL®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- 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 625mg, 750mg tablets
metformin ER (generic for Fortamet)
metformin (generic for Glumetza)
metformin solution (generic for Riomet)
Riomet®
Riomet ER®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ORAL HYPOGLYCEMICS – COMBINATIONS

Drug Class: Oral Hypoglycemics – Combinations

Preferred Agents: *No Prior Authorization required (except for agents containing DPP-4 indicated with *)*

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

Clinical PA Criteria For Preferred Agents That Contain A DPP-4 Inhibitor (indicated by leading *):

- Discontinuation of GLP-1 agonists

Non-Preferred Agents: *Prior Authorization Criteria below (**Agents That Contain A DPP-4 Inhibitor (indicated by leading *))**

Actoplus Met®
*alogliptin/metformin
*alogliptin/pioglitazone
dapagliflozin/metformin ER
Duetact®
glipizide/metformin
*Glyxambi®
Invokamet®/Invokamet XR®
*Kazano®
*linagliptin and metformin hydrochloride
*Oseni®
pioglitazone/glimepiride
pioglitazone/metformin
*Qtern®
*saxagliptin/metformin ER
*sitagliptin/metformin
*sitagliptin/metformin ER
Segluromet®
*Steglujan®
*Trijardy XR
*Zituvimet®/Zituvimet XR®

Non-Preferred Agent PA Criteria:

- Discontinuation of GLP-1 agonists (Only applies to products that contain a DPP-4 inhibitor); **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class

QUANTITY LIMITS

Janumet® (sitagliptin / metformin)	2 tablets per day

❒ **Duration of Approval**: 1 year

ORAL HYPOGLYCEMICS – DPP4 INHIBITORS

Drug Class: Oral Hypoglycemics – DPP4 Inhibitors

Preferred Agents: *Clinical Prior Authorization below*

Januvia®
Tradjenta®

Clinical Preferred Agent PA Criteria:

- Discontinuation of GLP-1 agonists

Non-Preferred Agents: *Prior Authorization Criteria below*

alogliptin
Brynovin® (sitagliptin)
Nesina®
saxagliptin
sitagliptin (generic for Zituvio®)
Zituvio®

Non-Preferred Agent PA Criteria:

- Discontinuation of GLP-1 agonists; **AND**
- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Therapeutic failure with a one-month trial with two preferred medications within the same class
- **See additional medication-specific criteria below**:

Clinical PA Criteria applies to Listed Agents Below

BRYNOVIN® (SITAGLIPTIN)

- Patient has difficulty swallowing

QUANTITY LIMITS

Brynovin® (sitagliptin)	4ml/day
Januvia® (sitagliptin phosphate)	100mg/day max daily dose limit; quantity limit of 1 tablet – any strength per day
TRADJENTA 5 MG TABLET	5mg per day

❒ **Duration of Approval**: 1 year

ORAL HYPOGLYCEMICS – MEGLITINIDES

Drug Class: Oral Hypoglycemics – Meglitinides

Preferred Agents: *No Prior Authorization required*

nateglinide
repaglinide

❒ **Duration of Approval**: 1 year

ORAL HYPOGLYCEMICS – SGLT2 INHIBITORS

Drug Class: Oral Hypoglycemics – SGLT2 Inhibitors

Preferred Agents: *No Prior Authorization required*

Farxiga®
Jardiance®

Non-Preferred Agents: *Prior Authorization Criteria below*

dapagliflozin
Inpefa®
Invokana®
Steglatro®

Non-preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

ORAL HYPOGLYCEMICS – THIAZOLIDINEDIONES

Drug Class: Oral Hypoglycemics – Thiazolidinediones

Preferred Agents: *No Prior Authorization required*

pioglitazone

Non-Preferred Agents: *Prior Authorization Criteria below*

Actos®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

OSTEOPOROSIS AGENTS: BISPHOSPHONATES

Drug Class: Osteoporosis Agents: Bisphosphonates

Preferred Agents: *No Prior Authorization required*

alendronate sodium

Non-Preferred Agents: *Prior Authorization Criteria below*

Actonel®
alendronate sodium oral solution
Atelvia®
Binosto®
Boniva®
Fosamax®
Fosamax Plus D®
Ibandronate
risedronate (Actonel)
risedronate (Atelvia)

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- See additional medication-specific criteria below:

Quantity Limitations:

Atelvia® (risedronate) – brand & generic	4 per 30 days
Actonel® (risedronate)	35mg - 4 per 28 days

Duration of Approval: 1 year

OSTEOPOROSIS AGENTS: OTHER

Drug Class: Osteoporosis Agents: Other

Preferred Agents: *No Prior Authorization required (except for agents listed under Clinical PA Criteria)*

calcitonin nasal spray
Forteo®

Non-Preferred Agents: *Prior Authorization Criteria below*

Bonsity (teriparatide)
teriparatide
Tymlos®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications
- **See additional medication-specific criteria below:**

Clinical PA Criteria applies to Listed Agents Below

BONSITY® (TERIPARATIDE)

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures
- Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture
- Length of authorization: maximum cumulative duration of 2 years per lifetime, unless clinical documentation is provided showing patient remains at or has returned to having a high risk for fracture

FORTEO® (TERIPARATIDE)

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures
- Increase of bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fractures
- Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture

- Length of authorization: maximum cumulative duration of 2 years per lifetime, unless clinical documentation is provided showing patient remains at or has returned to having a high risk for fracture

TYMLOS® (ABALOPARATIDE) – PDL CRITERIA DOES NOT APPLY

- Treatment of osteoporosis in postmenopausal women who are at high risk for fractures; **OR**
- Treatment of osteoporosis in men who are at high risk for fractures
- Length of authorization: maximum cumulative duration of 2 years per lifetime (includes any prior use of Forteo)

Duration of Approval: 1 year (Forteo and Tymlos – maximum 2 years per lifetime)

OSTEOPOROSIS AGENTS: SERMS

Drug Class: Osteoporosis Agents: SERMs

Preferred Agents: *No Prior Authorization required*

raloxifene

Non-Preferred Agents: *Prior Authorization Criteria below*

Evista®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications
- Contraindication or drug to drug interaction with the preferred medications
- History of unacceptable side effects
- Trial and failure with six months with one preferred medication
- Unique FDA approved indication not included in preferred medications

❒ **Duration of Approval**: 1 year

OTIC ANTIBIOTICS

Drug Class: Otic Antibiotics

Preferred Agents: *No Prior Authorization required*

ciprofloxacin-dexamethasone (generic for Ciprodex®)
neomycin-polymyxin-HC ear soln/susp
ofloxacin otic

Non-Preferred Agents: *Prior Authorization Criteria below*

ciprofloxacin otic
ciprofloxacin-fluocinolone (generic for Otovel®)
ciprofloxacin-hydrocortisone (generic for Cipro HC ®)
Cipro HC®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Therapeutic failure (duration = 3 days) with one preferred medication

Duration of Approval: 1 year for all other medications

OTIC QUINOLONES

Drug Class: Otic Quinolones

Preferred Agents: *No Prior Authorization required*

Ciprodex®
ciprofloxacin-dexamethasone (generic for Ciprodex®)
ofloxacin otic

Non-Preferred Agents: *Prior Authorization Criteria below*

ciprofloxacin otic
ciprofloxacin-fluocinolone (generic for Otovel®)
Cipro HC®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Therapeutic failure (duration = 3 days) with one preferred medication

Duration of Approval: 1 year for all other medications

OXAZOLIDINONES

Drug Class: Oxazolidinones

Preferred Agents: *No Prior Authorization required*

Linezolid tablets

Non-Preferred Agents: *Prior Authorization Criteria below*

Linezolid suspension
Sivextro®
Zyvox®

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medication
- Contraindication or drug to drug interaction with the preferred medication
- History of unacceptable side effects
- **See additional medication-specific criteria below**:

SIVEXTRO® (TEDIZOLID PHOSPHATE)

For diagnosis of non-purulent cellulitis

- Trial, failure or intolerance to first line beta lactam therapy **and**
- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (SMZ/TMP), tetracycline (minocycline or doxycycline) **or**
- Culture and *sensitivity* results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

For diagnosis of purulent cellulitis, abscess, or wound infection:

- Trial, failure or intolerance to at least two of the following agents: clindamycin, sulfamethoxazole/trimethoprim (smz/tmp), tetracycline (minocycline or doxycycline) **or**
- Culture and sensitivity results demonstrate resistance to first line agents **or**
- Contraindication or intolerance to all other treatment options

Quantity Limitations:

Linezolid tabs *(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: 300mg and 500mg Tablet, 300mg Tablet for Suspension

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: sickle-cell disease
- ❒ **Duration of approval**:
  - **Initial authorization**: 12 months
  - **Continuation of Therapy**: 12 months
- ❒ **Prescriber Specialty**: Prescribed by, or in consultation, with a hematologist or other specialist with expertise in the diagnosis and management of sickle cell disease
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Baseline hemoglobin level between 5.5 g/dL and 10.5g/dL **AND**
- ❒ **Age**:
  Oxbryta 300mg tablet: ≥ 4 years of age
  Oxbryta 500mg tablet: ≥ 12 years of age
  Oxbryta 300mg tablet for suspension: ≥ 4 years of age
- ❒ **Quantity**: 90 tablets/30 days
- ❒ **Route of Administration**: oral
- ❒ **Place of Service**: outpatient

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Patient must show an increase in hemoglobin level from initial baseline **OR**
  - Provider attests to other positive clinical response

OXERVATE™ (CENEGERMIN-BKBJ)

Drug Class: Recombinant human nerve growth factor (rhNGF)

FDA-approved uses: Indicated for the treatment of neurotrophic keratitis

Available dosage forms: Ophthalmic solution, 0.002% (per mL)

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: FDA approved indications as listed above
- ❒ **Duration of approval**:
  - **Initial authorization**: 56 days
- ❒ **Prescriber Specialty**: Prescribed by, or in consultation with, an ophthalmologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Attestation that the patient or caregiver has been counseled on proper administration technique
  - Documentation that the member has a diagnosis of stage 2 (recurrent/persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis in affected eye(s)
  - Documentation that the member has tried and failed at least two conventional non-surgical treatments (e.g. preservative-free artificial tears, lubricant eye ointment, topical antibiotic eye drops, therapeutic contact lenses)
- ❒ **Quantity**: 28 vials every 28 days for the treatment of one eye (additional quantities may be approved for the treatment of the second eye when appropriate). Total of 8 kits (1 kit = 7 multi-dose vials) per affected eye per lifetime.
- ❒ **Age**: 2 years of age or older
- ❒ **Route of Administration**: Topical eye drop

PALFORZIA / PEANUT ALLERGEN POWDER-DNFP

Drug Class: Allergenic Extracts

FDA-approved uses: Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut

Available dosage forms: Powder for oral administration supplied in 0.5 mg 1 mg, 10 mg, 20 mg and 100 mg Capsules or 300 mg Sachets.

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Peanut allergy
- ❒ **Duration of approval**:
  - **Initial authorization**: 1 year
  - **Continuation of Therapy**: 1 year
- ❒ **Prescriber Specialty**: Allergy or Immunology specialist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Documented clinical history of allergy to peanuts or peanut-containing foods
  - A confirmed peanut diagnosis based on one of the following:
    - Peanut skin prick test >8mm
    - Serum IgE to peanut ≥14 kUA/L
    - A reaction that required epinephrine or ED visit
  - Used in conjunction with a peanut-avoidant diet
  - Patient has been prescribed and/or has a refill history of epinephrine auto-injector
  - Prescriber, health care setting, pharmacy, patient must meet manufacturer's REMS requirements
- ❒ **Age**: 1 year to 17 years of age
  - Patients who start therapy prior to 18 years of age may continue therapy

Criteria for continuation of therapy:

- ❒ Positive response to treatment as documented by at least ONE (1) of the following compared to pre-treatment:
  - Reduction in severe allergic reactions
  - Reduction in epinephrine use
  - Reduction in physician/clinic visits due to peanut allergy (physician office/ER visits/hospitalizations)
  - Improvement in quality of life or productivity

Contraindications/Exclusions/Discontinuation:

- History of severe or life-threatening episode of anaphylaxis or anaphylactic shock within 60 days
- Uncontrolled asthma
- History of eosinophilic esophagitis (EoE); other eosinophilic gastrointestinal disease; chronic, recurrent, or severe gastroesophageal reflux disease (GERD); symptoms of dysphagia or recurrent gastrointestinal symptoms of undiagnosed etiology
- History of a mast cell disorder, including mastocytosis, urticarial pigmentosa, and hereditary or idiopathic angioedema
- History of cardiovascular disease, including uncontrolled or inadequately controlled hypertension

PANCREATIC ENZYMES

Drug Class: Pancreatic Enzymes

Preferred Agents: *Clinical Prior Authorization below*

Creon®
Zenpep®

Clinical PA Criteria:

- Cystic fibrosis or chronic pancreatic insufficiency.

Non-Preferred Agents: *Prior Authorization Criteria below*

Pertzye®
Viokace®

Non-Preferred Agent PA Criteria:

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

PERTZYE®, VIOKACE® ***(LIPASE/PROTEASE/AMYLASE)***

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

Duration of Approval: 1 year

PHOSPHATE DEPLETERS

Drug Class: Phosphate Depleters

Preferred Agents: *Clinical Prior Authorization below*

calcium acetate capsules and tablets
sevelamer carbonate tablets (generic for Renvela)

Clinical PA Criteria:

- Diagnosis of chronic kidney disease

Non-Preferred Agents: *Prior Authorization Criteria below*

Auryxia®
ferric citrate
Fosrenol® / Fosrenol® powder pak
lanthanum
Renvela powder pkts and tablets
sevelamer carbonate powder pkts (generic for Renvela)
sevelamer tablets (generic for Renagel)
Velphoro®
Xphozah®

Non-Preferred Agent PA Criteria:

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

VELPHORO®

- Trial on two preferred medications.

XPHOZAH®

- Trial of two preferred medications
- Patient is currently receiving dialysis

❒ **Duration of Approval**: 1 year

PHOSPODIESTERASE-4 (PDE-4) INHIBITORS

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

Preferred Agents: Clinical Prior Authorization below

Roflumilast (generic for Daliresp)

ROFLUMILAST

- Severe COPD associated with chronic bronchitis and a history of exacerbations**; AND**
- Trial/failure on at least one first-line or second-line agent**; AND**
- Adjunctive therapy (roflumilast must be used in conjunction with first-line or second-line agent)

Non-Preferred Agents: *Prior Authorization Criteria below*

Daliresp®

Non-Preferred Agent PA Criteria:

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

DALIRESP® (ROFLUMILAST)

- Severe COPD associated with chronic bronchitis and a history of exacerbations**; AND**
- Trial/failure on at least one first-line or second-line agent**; AND**
- Adjunctive therapy (Daliresp® must be used in conjunction with first-line or second-line agent)

Duration of Approval: 1 year

PLATELET AGGREGATION INHIBITORS

Drug Class: Platelet Aggregation Inhibitors

Preferred Agents: *No Prior Authorization required*

Brilinta®
clopidogrel
prasugrel

Non-Preferred Agents: *Prior Authorization Criteria below*

aspirin/dipyridamole
dipyridamole
Effient®
Plavix®
ticagrelor

Non-Preferred Agent PA Criteria:

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

EFFIENT® *(PRASUGREL)*

- Due to a black box warning related to increase in risk of bleeds in patients > 75
- PDL criteria must be met and the MD will need to document medical necessity or clinical rationale for consideration.

Duration of Approval: 1 year

POTASSIUM BINDERS

Drug Class: Potassium Binders

Preferred Agents: *No Prior Authorization required*

Lokelma® powder packets
sodium polystyrene sulfonate oral powder
SPS Suspension
kionex suspension

Non-Preferred Agents: *Prior Authorization Criteria below*

Veltassa® oral powder packets

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

PRETOMANID® (PRETOMANID)

Drug Class: Nitroimidazole Antibiotic

FDA-approved uses: Pretomanid is indicated as part of a combination regimen with bedaquiline and linezolid, for the treatment of adults with pulmonary extensively drug resistant (XDR) treatment-intolerant, or nonresponsive multidrug=resistant (NDR) tuberculosis (TB).

Available dosage forms: 200mg oral tablets, taken with food.

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Pulmonary extensively drug resistant (XDR) or treatment intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)
- ❒ **Prescriber Specialty**: Prescribed by or in consultation with an infectious disease specialist or pulmonologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    - Diagnosis of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB); AND
    - Patient is concomitantly taking bedaquiline (Sirturo) and linezolid (Zyvox) as part of the recommended dosing regimen and use of bedaquiline and linezolid are not contraindicated in patient

Duration of Approval: 6 months

PROGESTATIONAL AGENTS

Drug Class: Progestational Agents

Preferred Agents:

medroxyprogesterone (oral)
progesterone (oral)
norethindrone (oral)

Non-Preferred Agents: *Prior Authorization Criteria below*

Crinone® (vaginal)
progesterone (intramuscular)
Prometrium® (oral)
Provera® (oral)

Non-Preferred Agent PA Criteria:

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

CRINONE® (*PROGESTERONE VAGINAL)*

- Excluded for diagnosis of fertility

Duration of Approval: 1 year

PROGESTINS FOR CACHEXIA

Drug Class: Progestins for Cachexia

Preferred Agents: *No Prior Authorization required*

megestrol oral suspension (generic Megace®)

Non-Preferred Agents: *Prior Authorization Criteria below*

megestrol oral suspension (generic Megace ES®)

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

PROTON PUMP INHIBITORS

Drug Class: Proton Pump Inhibitors

Preferred Agents: *No Prior Authorization required*

Nexium® susp pkts
omeprazole (Rx) capsules
pantoprazole tablets
Protonix® suspension

Non-Preferred Agents: *Prior Authorization Criteria below*

Dexilant® caps
dexlansoprazole
esomeprazole magnesium capsules, susp pkts
esomeprazole magnesium OTC caps, tabs
Konvomep®
lansoprazole caps, ODT
lansoprazole OTC caps
Nexium® capsules
omeprazole OTC caps, tabs, ODT
omeprazole/sodium bicarbonate caps, susp pkts
pantoprazole suspension
Prevacid caps, solutabs
Prilosec® susp
Protonix® tablets
Rabeprazole tabs
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*

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

Clinical PA Criteria:

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Adcirca®
bosentan tablets (generic for Tracleer)
bosentan susp. (generic for Tracleer)
Letairis®
Liqrev®
Opsynvi®
Orenitram ER®
Orenitram Titration Kit
Revatio® suspension
Revatio® tablets
Tadliq®
Tracleer® suspension
Tyvaso DPI®
Winrevair
Yutrepia® (Treprostinil sodium)

Non-Preferred Agent PA Criteria:

- Diagnosis of pulmonary hypertension**; AND**
- Must be prescribed by or in consultation with a cardiologist or pulmonologist; **AND**
- Allergy to the preferred medications; **OR**
- Contraindication or drug to drug interaction with the preferred medications; **OR**
- History of unacceptable side effects; **OR**
- Therapeutic failure with one-month trial of one preferred medication
- **See additional medication-specific criteria below**

OPSYNVI® *(MACITENTAN/TADALAFIL)*

- Patient is ≥ 18 years of age

- Quantity limit: 1 per day

TADLIQ® *(TADALAFIL)*

- Patient is ≥ 18 years of age

WINREVAIR® *(SOTATERCEPT-CSRK)*

- Diagnosis of PAH WHO group 1, functional class II or III**; AND**
- Documented trial and failure of, or contraindication to, at least 2 months of combination therapy including one PDE-5 inhibitor AND one ERA; **AND**
- Winrevair is being used as add on therapy to standard care**; AND**
- Platelet count of > 50,000/mm3 (> (>50x10^9/L), acceptable hemoglobin levels, and other labs in accordance with the product label; **AND**
- Counseling has occurred regarding the need for effective contraception due to risk of embryo-fetal toxicity, and the risk of impaired fertility with use of this medication

YUTREPIA® *(TREPROSTINIL SODIUM)*

- Patient is ≥ 18 years of age; **AND**
- Therapeutic failure with one month trial of preferred trepostinil sodium (e.g., Tyvaso Solution)

Duration of Approval: 1 year

PULMOZYME® / DORNASE ALPHA

Drug Class*:* Mucolytics

FDA-approved uses:

- ❒ In conjunction with standard therapies for the management of cystic fibrosis (CF) patients to improve pulmonary function.
- ❒ To reduce the risk of respiratory tract infections requiring parenteral antibiotics in CF patients with an FVC ≥ 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**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects**; OR**
- Infection is caused by an organism that is resistant to the NO PA REQUIRED quinolone medications**; OR**
- Trial/failure (duration = 3 days) of any two preferred quinolone medications**; OR**
- Antibiotic therapy initiated in hospital
- **See additional medication-specific criteria below:**

MOXIFLOXACIN

- PDL criteria and quantity limit do not apply when used for the treatment of active drug-susceptible pulmonary tuberculosis for patients ≥12 years of age.
- Length of approval = 17 weeks when used for the treatment of active drug-susceptible pulmonary tuberculosis

Quantity Limitations:

Cipro® tabs (ciprofloxacin)	56 per fill
ciprofloxacin (Cipro®)	56 per fill
levofloxacin tabs (Levaquin®)	250MG - 28 per fill 500mg - 28 per fill 750mg - 14 per fill
moxifloxacin (Avelox®)	21 per fill

Duration of Approval: Date of service; if needed, longer lengths may be approved for transplant recipients

RANOLAZINE / RANEXA, ASPRUZYO SPRINKLE

Drug Class: Antianginal and Anti-ischemic Agents, Non-hemodynamic

FDA-approved uses: treatment of chronic angina

Available dosage forms:

- Ranolazine 500 mg and 1000 mg extended-release tablets
- Ranexa® 500 mg and 1000 mg extended-release tablets
- Aspruzyo Sprinkle® 500 and 1000 mg extended-release granules

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: chronic stable angina
- ❒ **Duration of Approval**:
  - **Initial Authorization:** 6 months
  - **Continuation of Therapy:** 12 months
- ❒ **Prescriber Specialty**: prescribed by, or in conjunction with, a cardiologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):

Ranolazine ER (RANEXA®)

- Current progress notes supporting past medication usage, including at least 1 formulary anti-anginal agent from ALL 3 different drug classes:
  - **Beta Blocker**: acebutolol, atenolol, carvedilol, metoprolol, nadolol, propranolol
  - **Calcium Channel Blocker**: amlodipine, diltiazem, felodipine, isradipine, nifedipine, nicardipine, verapamil
  - **Long-Acting Nitrate**: isosorbide dinitrate, isosorbide mononitrate, nitroglycerin patch
- Labs and medical records supporting indicated diagnosis of chronic angina
- Medical record detailing that Ranexa will be used in addition (add-on) to another anti-anginal medication (i.e., beta-blocker, calcium channel blocker, long-acting nitrate) or patient has contraindications to beta-blockers, calcium channel blockers AND long-acting nitrates

Aspruzyo Sprinkle® (ranolazine)

- All the above criteria are met
- Contraindication to ranolazine (Ranexa) ER tablets due to swallowing difficulties **OR**
- Administration via nasogastric (NG) or gastric tube

- ❒ **Quantity**: 60 tablets or 60 sachets every 30 days (500 mg PO BID initially; may increase to 1,000 mg PO BID)
- ❒ **Age**: 18 years of age or older
- ❒ **Route of Administration**:
  - oral - extended-release tablet or granules
  - via NG/gastric tube with extended-release granules (Aspruzyo)

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
    - Current medical records and labs to determine safety and efficacy of treatment

Contraindications/Exclusions/Discontinuation:

- ❒ Hepatic impairment (Child-Pugh Classes A and B)
- ❒ Combined administration with other drugs that are strong inhibitors of CYP3A including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir
- ❒ Combined administration with other drugs that are inducers of CYP3A including rifampin, rifabutin, phenobarbital, phenytoin, carbamazepine, and St. John's wort
- ❒ Moderate to severe renal impairment CrCl < 60mL/min

Other special considerations:

- Not for initial therapy because it can increase QT interval

SANDOSTATIN® / OCTREOTIDE

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

Drug Class: Somatostatic Agents

FDA-approved uses:

- ❒ **Acromegaly**
  Octreotide Acetate Injection is indicated to reduce blood levels of growth hormone and IGF-I (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.
- ❒ **Carcinoid Tumors**
  Octreotide Acetate Injection is indicated for the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease.
- ❒ **Vasoactive Intestinal Peptide Tumors (VIPomas)**
  Octreotide Acetate Injection is indicated for the treatment of the profuse watery diarrhea associated with VIP-secreting tumors.

Available dosage forms: Vial 50 mcg/mL, 100 mcg/mL, 200 mcg/mL, 1000 mcg/mL

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses:**
  - Acromegaly
  - Metastatic VIP
  - Chemo/radiation
  - HIV/AIDS-induced diarrhea
  - Metastatic carcinoid tumors
  - Carcinoid tumors
- ❒ **Duration of Approval:**
  - **Initial Authorization**: 6 months
  - **Continuation of Therapy**: 1 year
- ❒ **Prescriber Specialty:** Prescribed by, or in consultation with, an endocrinologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis confirmed
  - Prescribed by, or in consultation with, an endocrinologist
- ❒ **Age:** 18 years of age or older
- ❒ **Route of Administration:** Subcutaneous, intramuscular injection

Criteria for continuation of therapy:

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - The above criteria has been met
  - Requires decreased or normalized IGF-1 levels

SENSIPAR® / CINACALCET

Drug Class: Calcimimetic, Parathyroid Calcium Receptor Sensitivity Enhancer

FDA-approved uses:

- ❒ **Hyperparathyroidism, primary:** Treatment of severe hypercalcemia in adult patients with primary hyperparathyroidism for who parathyroidectomy would be indicated on the bases of serum calcium levels, but who are unable to undergo parathyroidectomy.
- ❒ **Hyperparathyroidism, secondary:** Treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on dialysis.
- ❒ **Limitation of use:** Not indicated for use in patients with CKD who are not on dialysis (due to increased risk of hypocalcemia)
- ❒ **Parathyroid carcinoma**: Treatment of hypercalcemia in adult patients with parathyroid carcinoma.

Available dosage forms: Tablet 30 mg, 60 mg, 90 mg

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses:** FDA Approved Indication as listed above and above
- ❒ **Duration of Approval:**
  - **Initial Approval:** 6 months
  - **Continuation of Therapy:** 12 months
- ❒ **Prescriber Specialty:**
  Nephrologist, Endocrinologist,
  Oncologist or prescriber in
  consultation with specialist.
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **For Secondary hyperparathyroidism due to CKD on dialysis**:
    - Patient is at least 18 years of age, **AND**
    - Trial, failure, or intolerance to an approved formulary phosphate binder trial, **AND**
    - Trial, failure or intolerance to calcitriol or Vitamin D analogs for a minimum of a three-month trial
  - **Labs:**
    - iPTH, calcium, renal function, serum phosphorus. iPTH levels must be > 300 (biPTH >160) and Ca > 8.4 in order to initiate therapy.
  - **For Parathyroid carcinoma (PC)**:
    - Patient is at least 18 years of age, **AND**
  - **Labs:**
    - Confirmation the patient has hypercalcemia as defined by baseline serum calcium (Ca) >10mg/dL (corrected for albumin)

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies): continued
    - **For Primary hyperparathyroidism**:
        - Patient is at least 18 years of age, **AND**
        - Confirmation the parathyroidectomy is indicated by patient is unable to undergo parathyroidectomy
    - **Labs:**
        - Severe hypercalcemia as defined by baseline (pre-treatment) serum calcium (Ca) >12 mg/dL (corrected for albumin)

Criteria for continuation of therapy:

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    - Absence of unacceptable toxicity from the drug (e.g., hypocalcemia, seizures, hypotension, worsening heart failure, arrhythmia, adynamic bone disease); **AND**

    - **Secondary Hyperparathyroidism (HPT)**
        - Adequate documentation of disease response as indicated by improvement of intact parathyroid hormone (iPTH) levels from baseline; **AND**
        - Current intact parathyroid hormone (iPTH) >150 pg/ml; **AND**
        - Current serum calcium (Ca) >7.5 mg/dL and the patient does not have symptoms of hypocalcemia

    - **Parathyroid Carcinoma (PC)**
        - Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
        - Current serum calcium (Ca) >8.4 mg/dL

    - **Primary Hyperparathyroidism (HPT)**
        - Adequate documentation of disease response as indicated by improvement of serum calcium (Ca) from baseline; **AND**
        - Current serum calcium (Ca) >8.4 mg/dL

Contraindications/Exclusions/Discontinuation:

- ❒ Hypersensitivity to any components of Sensipar
- ❒ Hypocalcemia
- ❒ In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

SIRTURO®/ BEDAQUILINE

Drug Class Antitubercular - Diarylquinoline Antibiotics

FDA-approved uses: Multi-drug resistant tuberculosis (MDR-TB)

Available dosage forms: Tablets: 20mg, 100mg

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Multi-drug resistant tuberculosis (MDR-TB)
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Patient must be under observed therapy

SKELETAL MUSCLE RELAXANTS

Drug Class: Skeletal Muscle Relaxants

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

baclofen tablets
baclofen oral solution (Ozobax)
cyclobenzaprine
methocarbamol 500mg and 750mg tablets
orphenadrine citrate
tizanidine tablets

BACLOFEN ORAL SOLUTION (*OZOBAX*)

- Allow if patient has swallowing difficulties.

Non-Preferred Agents: *Prior Authorization Criteria below*

Amrix®
baclofen suspension (generic Fleqsuvy)
cyclobenzaprine ER
chlorzoxazone
Dantrium®
dantrolene sodium
Fexmid®
Fleqsuvy®
Lorzone®
Lyvispah®
metaxalone
methocarbamol 1000mg tablet
Norgesic Forte®
orphenadrine-aspirin-caffeine
Tanlor®
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**

METHOCARBAMOL 1000MG TABLET

- **Bypass PDL criteria except require trial and failure of both PDL preferred methocarbamol 500mg and 750mg tablets**

Duration of Approval: 1 year

SODIUM PHENYLBUTYRATE AND TAURURSODIOL

Drug Class: ALS Agent- Histone deacetylase inhibitor

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

Available dosage forms: Sodium phenylbutyrate 3g/ taurursodiol 1 g packet

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: ALS
- ❒ **Duration of approval**:
  - **Initial authorization**: 1 year
  - **Continuation of Therapy**: 1 year
- ❒ **Prescriber Specialty**: Prescribed by or in consultation with a neurologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of ALS as determined by revised El Escorial criteria
  - Initiation of drug is within 18 months of symptom onset
  - Slow vital capacity (SVC) exceeding 60% of the predicted
  - Current use or has failed previous treatment with riluzole
- ❒ **Age**: ≥ 18 years old
- ❒ **QL**: 60 packets per 30 days

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Provider attestation of positive clinical response
  - Medication is prescribed at an FDA approved dose

SORIATANE® / ACITRETIN

Drug Class: Dermatological - Antipsoriatic Agents Systemic, Vitamin A Derivatives

FDA-approved uses: Severe Psoriasis

Available dosage forms: Capsules 10 mg, 17.5 mg, 25 mg

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses:** Moderate to Severe Psoriasis
- ❒ **Duration of Approval:**
  - **Initial Authorization:** 3 months
  - **Continuation of Therapy:** 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - 90 day trial of methotrexate **AND**
  - 90 day trial of high dose topical steroid (e.g. betamethasone augmented, clobetasol, halobetasol)
- ❒ **Prescriber Specialty:** Dermatology
- ❒ **Quantity:** Max 2 capsules per day
- ❒ **Route of Administration:** Oral

Criteria for continuation of therapy

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

Contraindications/Exclusions/Discontinuation:

- Soriatane must not be used by females who are pregnant, or who intend to become pregnant during therapy or at any time for at least 3 years following discontinuation of therapy.
- Soriatane is contraindicated in patients with impaired liver or kidney function and in patients with chronic abnormally elevated blood lipid values.
- Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:

- Pregnancy Category X.
- Soriatane should not be taken with methotrexate or tetracyclines.
- Soriatane should not be used in patients with known alcohol abuse.

SYNAGIS® / PALIVIZUMAB

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

Drug Class: Immunological Agent/Monoclonal Antibody

FDA-approved uses: Prevention of RSV for children <2yo at high risk of RSV disease
Respiratory syncytial virus (RSV) prophylaxis with palivizumab (Synagis®) **may be considered medically necessary** in the following infants and children **to a maximum of five monthly doses per RSV season**:

- ❒ **Prematurity:**
  - Infants who are younger than 12 months of age at the start of RSV season and are born before **29 weeks 0 days** gestation.
- ❒ **Chronic Lung Disease (CLD):**
  - Preterm infants younger than 12 months of age who develop CLD of prematurity (defined as gestational age <32 weeks, 0 days) and required >21% oxygen for at least the first 28 days after birth.
  - Infants between 12 and 24 months of age who developed CLD of prematurity as defined above and who continue to require medical support (chronic corticosteroid therapy, diuretic therapy, supplemental oxygen or bronchodilator therapy) within 6 months of the start of RSV season.
- ❒ **Heart Disease:**
  - Infants who are 12 months of age or younger with hemodynamically significant Congenital Heart Disease (CHD). Those children with CHD who are most likely to benefit from immunoprophylaxis include those with:
    - acyanotic heart disease who are receiving medication to control congestive heart failure (documentation required) and will require cardiac surgical procedures ; **or**
    - moderate to severe pulmonary hypertension; **or**
    - cyanotic heart disease (if recommended by a pediatric cardiologist).
  - Additionally, children younger than 24 months who undergo cardiac transplantation during the RSV season may be considered for prophylaxis.
- ❒ Immune prophylaxis for RSV **is considered not medically necessary** for
  - Infants and children with hemodynamically insignificant heart disease including but not limited to:
    - secundum atrial septal defect,
    - small ventricular septal defect,
    - pulmonic stenosis,
    - uncomplicated aortic stenosis,
    - mild coarctation of the aorta,
    - patent ductus arteriosus
    - Lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure.
    - Infants with mild cardiomyopathy who are not receiving medical therapy for the condition.

***Note**: Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a post-operative dose of palivizumab (15mg/kg) should be considered after cardiac bypass or at the conclusion of extra-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):
  - Children who have *not* had a dose of Beyfortus™ (nirsevimab) in the current RSV season; **AND**
  - Mother did not receive vaccination against RSV in the 2nd or 3rd trimester; **AND**
  - Infants who are younger than 12 months of age at the start of the Synagis season and who are born before 29 weeks, 0 days' gestation.
  - Infants in the first 12 months of life, who are diagnosed with CLD (chronic lung disease) of prematurity defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
  - Infants in the second year of life who are diagnosed with CLD (as per above criteria) **AND** who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy) within the 6-month period before the start of the second RSV season.
  - Children who are 12 months or younger with hemodynamically significant CHD as evidenced by:
    - acyanotic heart disease and are receiving medication to control congestive heart failure, and will require cardiac surgical procedures

- ❒ **Documentation Requirements continued** (e.g. Labs, Medical Record, Special Studies):
    - Infants with moderate to severe pulmonary hypertension. Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
    - Child younger than 24 months who will be profoundly immunocompromised during the RSV season.
- ❒ **Quantity:**
    - The recommended dose of Synagis is 15mg/kg body weight administered intramuscularly. Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children. For qualifying infants up to 5 doses per RSV season must be allowed. Qualifying infants born during the RSV season may require fewer doses.
- ❒ **Age:** 24 months and younger, See criteria for authorization for age specific indications.
- ❒ **Route of Administration:** Intramuscular

Criteria for continuation of therapy:

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    - Requests for coverage outside of RSV season will require authorization.

Contraindications/Exclusions/Discontinuation:

- History of severe prior reaction to palivizumab or any component of the formulation.
- In addition, drug therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy **OR** no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

Other special considerations:

- Routine use in cystic fibrosis and Down Syndrome is not recommended.
- The clinical reviewer, in his or her professional judgment, will override criteria when the requested item is medically necessary. In addition, because there is no definite evidence for the treatment of patients undergoing stem cell transplant or infants and children with Cystic Fibrosis, the approval of Synagis for these patients will be done on a case by case basis by the clinical reviewer.

References

The American Academy has issued updated guidance for the 2021-2022 season.
Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2021-2022 RSV Season (aap.org)

To see RSV virology trends by state/region, please click the link below:
https://www.cdc.gov/surveillance/nrevss/rsv/state.html

TAZAROTENE

Drug Class: Dermatological - Antipsoriatic Agents Topical

FDA-approved uses:
- Indicated for the topical treatment of plaque psoriasis and acne vulgaris

Available dosage forms:
Formulary:
- Tazarotene Cream, 0.05% and 0.1%
- Tazarotene Gel, 0.05% and 0.1%

Coverage Criteria/Limitations for initial authorization:
- ❒ **Diagnoses**: Psoriasis or acne vulgaris
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 12 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Prescribed to treat an FDA approved indication for Tazarotene **AND**
  - Diagnosis specific requirements:
    - For the treatment of psoriasis
      - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid
      - **OR**
      - Documented trial, failure, or intolerance of one low or medium potency topical steroid and justification for avoidance of a higher potency topical steroid **OR**
      - Topical steroid avoidance due to pediatric age **AND**
      - Documented trial, failure or intolerance to a topical vitamin D analogue (i.e. calcipotriene or calcitriol) or a clinical reason why both cannot be used.
    - For the treatment of acne vulgaris
      - Documented trial, failure or intolerance to one of the following:
        - Topical adapalene
        - Topical tretinoin
- ❒ **Quantity**: Appropriate amount to cover affected area for up to 34 days based on provider estimate or body surface area (BSA) estimate.
  - Prescribing information recommends a "thin layer" defined as 2 mg/cm^2 for approved diagnoses.

- ❒ **Age**:
  - Treatment of acne vulgaris: patients ≥ 12 years old
  - Treatment of psoriasis:
    - Cream – patients ≥ 18 years old
    - Gel – patients ≥ 12 years old

- ❒ **Route of Administration**: Topical

Criteria for continuation of therapy:

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

Contraindications/Exclusions/Discontinuation:

- ❒ Warning of embryofetal toxicity:
    - Use of topical retinoids should be avoided during pregnancy.
        - Females of child-bearing potential should have a negative pregnancy test within 2 weeks prior to initiating treatment and use an effective method of contraception during treatment.
        - If member is pregnant, Tazarotene is contraindicated and alternate therapy should be utilized.
- ❒ For the treatment of psoriasis in children, using the gel form, it is recommended to limit application to ≤ 20% of BSA.

TOPICAL ANTIBIOTICS

Drug Class: Topical Antibiotics

Preferred Agents: *No Prior Authorization required*

mupiricin ointment

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

Centany®
mupiricin cream
Xepi® Cream

Non-Preferred Agent PA Criteria:

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

XEPI® CREAM (*OZENOXACIN*)

- Quantity Limit = 2 tubes per month
- Length of authorization – 1 month

Duration of Approval: 1 year

TOPICAL STEROIDS – LOW POTENCY

Drug Class: Topical Steroids – Low Potency

Preferred Agents: *No Prior Authorization required*

hydrocortisone acetate cream
hydrocortisone acetate ointment
hydrocortisone/aloe
hydrocortisone cream
hydrocortisone lotion
hydrocortisone ointment

Non-Preferred Agents: *Prior Authorization Criteria below*

aclometasone dipropionate ointment and cream
Capex® Shampoo
Derma-smooth – FS ®
Desonide® ointment, cream, lotion
fluocinolone 0.01% oil
hydrocortisone solution
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
- Trial and failure of 14 days with **one** of the preferred medications

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

TOPICAL STEROIDS – MEDIUM POTENCY

Drug Class: Topical Steroids – Medium Potency

Preferred Agents: *No Prior Authorization required*

fluocinolone acetonide solution
fluticasone propionate cream
fluticasone propionate ointment
mometasone furoate ointment
mometasone furoate cream
mometasone furoate solution

Non-Preferred Agents: *Prior Authorization Criteria below*

Beser Kit
Beser Lotion
betamethasone valerate foam
clocortolone cream
fluocinolone acetonide cream
flurandrenolide lotion, ointment
fluticasone propionate lotion
hydrocortisone butyrate cream, lotion, ointment, solution
hydrocortisone valerate cream and ointment
Locoid® lotion
Locoid Lipocream®
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
- Trial and failure of 14 days with **one** of the preferred medications

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

TOPICAL STEROIDS – HIGH POTENCY

Drug Class: Topical Steroids – High Potency

Preferred Agents: *No Prior Authorization required*

betamethasone dipropionate cream, lotion, ointment
betamethasone valerate cream, lotion, ointment
fluocinonide cream, ointment, gel and solution
triamcinolone acetonide cream, lotion, ointment

Non-Preferred Agents: *Prior Authorization Criteria below*

amcinonide cream
betamethasone diproprionate augmented cream, gel
betamethasone diproprionate augmented lotion, ointment
clobetasol 0.025% cream
desoximetasone cream, ointment, gel, and spray
diflorasone diacetate cream and ointment
Diprolene® ointment
fluocinonide emollient
halcinonide
Halog® cream, ointment, solution
Kenalog® aerosol
Topicort® cream, ointment, gel and spray
triamcinolone spray
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
- Trial and failure of 14 days with **one** of the preferred medications

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

TOPICAL STEROIDS – VERY HIGH POTENCY

Drug Class: Topical Steroids – Very High Potency

Preferred Agents: *No Prior Authorization required*

clobetasol propionate solution
clobetasol propionate 0.05% cream
clobetasol propionate ointment
halobetasol propionate cream
halobetasol propionate ointment

Non-Preferred Agents: *Prior Authorization Criteria below*

ApexiCon® E Cream
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®)
Olux®
Tovet Kit
Tovet Emollient
Ultravate® lotion

Non-Preferred Agent PA Criteria:

- Allergy to the preferred medications**; OR**
- Contraindication or drug to drug interaction with the preferred medications**; OR**
- History of unacceptable side effects
- Trial and failure of 14 days with **one** of the preferred medications

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

TRYVIO / APROCITENTAN

Drug Class: Endothelin Receptor Antagonist (ERA)

FDA-approved uses: Resistant Hypertension (RH)

Available dosage forms: 12.5 mg tablet

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Resistant Hypertension despite concurrent use of 3 or more antihypertensive drug classes
- ❒ **Duration of approval**:
  - **Initial authorization**: 1 year
  - **Continuation of Therapy**: 1 year
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation demonstrating failure to reach blood pressure goal despite concurrent use of 3 or more antihypertensive drug classes; **AND**
  - Clinical documentation demonstrating failure to reach blood pressure goal despite addition of a mineralocorticoid receptor antagonist (i.e., spironolactone OR eplerenone) to the current 3 drug regimen; **OR**
  - Contraindication (i.e. hyperkalemia, renal impairment, etc.) or drug to drug interaction (i.e. CYP3A4 Inhibitors, potassium-sparing diuretics, etc.) preventing the use of both spironolactone and eplerenone; **AND**
  - For patients who can become pregnant, the prescriber attests:
    - patient is not pregnant or lactating
    - patient has been counseled on the risk of major birth defects AND to use acceptable methods of contraception before treatment with TRYVIO, during treatment with TRYVIO, and for one month after treatment discontinuation;
- ❒ **Specialty**: Prescribed by or in consultation with a specialist with experience in the treatment of RH such as a cardiologist, nephrologist or endocrinologist
- ❒ **Quantity**: 1 tablet per day
- ❒ **Age**: 18 years of age and older

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - For patients who can become pregnant, prescriber attests patient is not pregnant or lactating
  - Clinical documentation demonstrates blood pressure improvement compared to baseline
  - Prescriber attests that patient has not experienced unacceptable adverse effects from TRYVIO therapy (i.e. hepatotoxicity, clinically significant anemia, clinically significant edema)

Contraindications/Exclusions/Discontinuation:

- Pregnancy/lactation

ULCERATIVE COLITIS – ORAL

Drug Class: Ulcerative Colitis – Oral

Preferred Agents: *No Prior Authorization required*

mesalamine (generic for Lialda)
Pentasa®
sulfasalazine/ sulfasalazine DR

Non-Preferred Agents: *Prior Authorization Criteria below*

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

Non-Preferred Agent PA Criteria:

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

Duration of Approval: 1 year

URINARY TRACT ANTISPASMODICS

Drug Class: Urinary Tract Antispasmodics

Preferred Agents: *No Prior Authorization required*

fesoterodine ER
Myrbetriq®
oxybutynin / oxybutynin ER
solifenacin
tolterodine/ tolterodine ER
trospium

Non-Preferred Agents: *Prior Authorization Criteria below*

darifenacin ER
Detrol®/ Detrol LA®
Ditropan XL®
flavoxate HCL
Gemtesa®
mirabegron ER
Oxytrol®
Toviaz®
trospium ER
Vesicare®
Vesicare LS Suspension®

Non-Preferred Agent PA Criteria:

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

❒ **Duration of Approval**: 1 year

UTERINE DISORDER TREATMENTS

Drug Class: Uterine Disorder Treatments

Preferred Agents: *Clinical Prior Authorization below*

Myfembree®
Oriahnn®
Orilissa®

ORIAHNN® (ELAGOLIX/ESTRADIOL/NORETHINDRONE)

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
- Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C)**; AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss**; AND**
- Quantity limit: 56 tablets per 28 days

ORILISSA® (ELAGOLIX) 150MG

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis; **AND**
- Failure on an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C)**; AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss**; AND**
- Quantity limit: 28 tablets per 28 days

ORILISSA® (ELAGOLIX) 200MG

- Patient ≥ 18 years old; **AND**
- Confirmed diagnosis of endometriosis with dyspareunia; **AND**
- Failure on an adequate trial of the following therapies:
  - Non-steroidal anti-inflammatory drugs (NSAIDs); **AND**
  - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C)**; AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss**; AND**
- Treatment duration of Orilissa 200mg twice daily has not exceeded a total of 6 months**; AND**
- Quantity limit: 56 tablets per 28 days

MYFEMBREE® (RELUGOLIX/NORETHINDRONE)

- Patient ≥ 18 years old; **AND**
- Patient is premenopausal; **AND**
- Confirmed diagnosis of
  - Uterine leiomyomas (fibroids) with heavy menstrual bleeding; **AND**
  - Failure on an adequate trial of hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device)**; OR**
  - Moderate to severe pain associated with endometriosis; **AND**
  - Failure on an adequate trial of the following therapies:
    - Non-steroidal anti-inflammatory drugs (NSAIDS)**; AND**
    - Hormonal contraceptives (including oral or transdermal formulations, vaginal ring or intrauterine device); **AND**
- Prescribed by or in consultation with an obstetrics/gynecology or reproductive specialist; **AND**
- Pregnancy is excluded prior to treatment; **AND**
- Patient will use effective non-hormonal contraception during treatment with requested medication and one week after stopping therapy; **AND**
- Patient does not have osteoporosis; **AND**
- Patient does not have severe hepatic impairment (Child Pugh C)**; AND**
- Patient has not completed a previous course of hormonal treatment that could contribute to bone loss; **AND**
- Quantity limit: 28 tablets per 28 days

❒ **Duration of Approval**:

- Oriahnn, Orilissa 150mg and Myfembree = 1 year (maximum total duration of 24 months)
- Orilissa 200mg = 6 months (maximum duration)

VAGINAL ANTIBIOTICS

Drug Class: Vaginal Antibiotics

Preferred Agents: *No Prior Authorization required*

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

Non-Preferred Agents: *Prior Authorization Criteria below*

Cleocin (clindamycin) 2% Cream
metronidazole 1.3% Gel
Vandazole (metronidazole) 0.75% Gel
Xaciato (clindamycin) 2% Gel

Non-Preferred Agent PA Criteria:

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

XACIATO® *(CLINDAMYCIN)*

- Patient age is 12 years or older

❒ **Duration of Approval**: 6 months

VEMLIDY / TENOFOVIR ALAFENAMIDE

Drug Class: Anti-Retroviral – Nucleotide Reverse Transcriptase Inhibitor

FDA-approved uses: Treatment of Chronic Hepatitis B Infection

Available dosage forms: Tablet 25 mg

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Chronic Hepatitis B Infection
- ❒ **Duration of approval**:
    a. **Initial authorization**: 6 months
    b. **Continuation of Therapy**: 12 months

- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
    a. Diagnosis of Chronic Hepatitis B infection with compensated liver disease; **AND**
    b. Trial, failure, or contraindication to Entecavir; **AND**
    c. Trial of tenofovir disoproxil fumarate unless one of the following conditions are met:
        i. History of osteoporosis or osteopenia
        ii. Renal impairment defined by creatinine clearance (CrCl) < 50 mL/min or history of chronic renal disease.
        iii. Trial of tenofovir disoproxil fumarate is inappropriate; **OR**
    d. Persistent viremia or breakthrough infection while taking lamivudine **or** adefovir [*NOTE: lamivudine and adefovir are no longer recommended in current guidelines*]; **AND**
    e. Attestation: Confirmation of no HIV risk or negative HIV status
- ❒ **Quantity**: 30 tablets per 30 days
- ❒ **Age**: 6 and older

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
    a. Confirmation of positive clinical response.
    b. Confirmation of continued monitoring according to available guidelines (i.e. HBV DNA, ALT, etc.)
    c. CrCl remains ≥ 15 mL/min

Contraindications/Exclusions/Discontinuation:

1. HIV and HBV coinfection: Should not be used as a single agent for the treatment of HIV due to resistance development risk
2. If HIV positive - provide further justification
3. For females: There have been no data reported to the antiretroviral registry related to the use of this drug in pregnancy. The Health and Human Services (HHS) Perinatal HIV Guidelines note data are insufficient to recommend tenofovir alafenamide for initial therapy in antiretroviral-naive pregnant women. Tenofovir disoproxil fumarate (Viread) preferred in pregnant women.
4. Therapy may be discontinued if patient is noncompliant with medical or pharmacologic therapy OR no demonstrable clinically significant improvement in condition has occurred after initiation of drug therapy.

VERQUVO / VERICIGUAT

Drug Class : soluble guanylate cyclase (sGC) stimulator

FDA-approved uses: To reduce the risk of cardiovascular death and heart failure (HF) hospitalization following a hospitalization for heart failure or need for outpatient IV diuretics, in adults with symptomatic chronic HF and ejection fraction less than 45%.

Available dosage forms: 2.5 mg, 5 mg, 10 mg tablets

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Symptomatic chronic heart failure with ejection fraction less than 45%
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: 12 months
- ❒ **Prescriber Specialty**: Cardiology, or prescribed in consult with cardiology
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Documentation that member has chronic heart failure, New York Heart Association [NYHA] Class II-IV who has had a decompensation while on standard therapy for heart failure
  - Documentation of a left ventricular ejection fraction (LVEF) of less than 45%
  - Documentation that member is currently taking or has a contraindication to ALL of the following:
    - ACE inhibitor or ARB or Entresto
    - Beta blocker
    - Oral diuretic (not applicable if member had IV diuretics in previous 3 months)
  - History of hospitalization for heart failure in the previous 6 months or required outpatient IV diuretics for heart failure in the previous 3 months.
  - For female patients of childbearing potential: Documentation of a negative pregnancy test in the previous 30 days and provider attestation that member has been counseled on the risks and advised to use contraception throughout treatment with and one month following Verquvo administration.
  - Prescriber attestation that member is not or will not be using VERQUVO concomitantly with other soluble guanylate cyclase (sGC) stimulators (e.g. riociguat) or PDE-5 inhibitors (e.g. sildenafil, tadalafil, vardenafil and avanafil).

- ❒ **Quantity**: maintenance dosing, 30 tablets per 30 days
- ❒ **Age**: 18 years or older
- ❒ **Route of Administration**: Oral

Criteria for continuation of therapy:

- ❒ Documentation that member has had no intolerable adverse effects from treatment
- ❒ Documentation that member is responding positively to treatment demonstrated by improvement or slowing of decline in signs and symptoms of heart failure.

Contraindications/Exclusions/Discontinuation:

VERQUVO is contraindicated in patients with concomitant use of other soluble guanylate 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.

VOQUEZNA (VONOPRAZAN)

Drug Class: potassium-competitive acid blocker

FDA-approved uses:

- healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults
- relief of heartburn associated with non-erosive Gastroesophageal reflux disease (GERD) in adults
- in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults – ***if the request is for treatment of H. pylori, please refer to the MHP Common Formulary Prior Authorization Criteria for H. Pylori Treatment; Non-preferred agents section***
- *in combination* with amoxicillin for the treatment of H. pylori infection in adults – ***if the request is for treatment of H. pylori, please refer to the MHP Common Formulary Prior Authorization Criteria for H. Pylori Treatment; Non-preferred agents section***

Available dosage forms:
Oral Tablet: 10 MG, 20 MG

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Erosive esophagitis; non-erosive gastroesophageal reflux disease (GERD); treatment of H. pylori infection* *(to review Voquezna requests to treat H. pylori, refer to MHP Common Formulary Prior Authorization Criteria for H. pylori treatment for Coverage Criteria/Limitations)*
- ❒ **Duration of approval**:
  - **Initial authorization**: 8 months
  - **Continuation of Therapy**: 6 months
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Diagnosis of erosive esophagitis; **OR**
  - Diagnosis of non-erosive gastroesophageal reflux disease (GERD); **AND**
  - Clinical documentation demonstrates patient had a therapeutic failure after one-month trial with one preferred proton pump inhibitor (PPI)
- ❒ **Quantity**: 1 tablet per day
- ❒ **Age**: 18 years of age and older

Criteria for continuation of therapy:

- ❒ Documentation Requirements (e.g. Labs, Medical Record, Special Studies):
  - Clinical documentation demonstrates significant improvement in signs and symptoms of erosive esophagitis or non-erosive gastroesophageal reflux disease (GERD)
  - Provider attests that continuation beyond the FDA-approved duration of therapy is medically necessary
  - Provider attests risks vs. benefits of continuation have been weighed and discussed with the patient (i.e. Risks of C. difficile-associated infection, fractures, fundic gland polyps, hypomagnesemia, tubulointerstitial nephritis, vitamin B12 deficiency, etc.)

VTAMA / TAPINAROF

Drug Class: Dermatological - Antipsoriatic Agents Topical

FDA-approved uses:

- An aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults and atopic dermatitis indications 2 years of age or older.

Available dosage forms:

- Cream, 1% (10mg/gram)

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Plaque psoriasis, Atopic dermatitis
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 12 months
- ❒ **Prescriber Specialty**: Prescribed by, or in consultation with, a dermatologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):

  - **Plaque Psoriasis:**
    - Prescribed to treat plaque psoriasis; **AND**
    - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid; **AND**
    - Documented trial, failure, or intolerance to topical calcipotriene, calcitriol, tazarotene, or combination products containing prior stated ingredients; **OR**
    - Clinical documentation as to why therapies listed above are not appropriate; **AND**
    - For quantities greater than 60 grams per 30 days, prescriber must attest that the volume of drug is necessary for adequate treatment of the patient

  - **Atopic Dermatitis:**
    - Prescribed to treat atopic dermatitis; **AND**
    - Documented trial, failure, or intolerance to at least one
    - topical steroid; **OR**
    - Clinical documentation as to why topical steroid therapy is not appropriate; **AND**
    - For quantities greater than 60 grams per 30 days, prescriber must attest that the volume of drug is necessary for adequate treatment of the patient

- ❒ **Quantity**: 1 tube (60 grams) per 30 days
- ❒ **Age**: For Plaque psoriasis: ≥ 18 years old; For Atopic dermatitis ≥ 2 years old

Criteria for continuation of therapy:

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

YORVIPATH/ PALOPEGTERIPARATIDE

Drug Class: Parathyroid Hormone Analog

FDA-approved uses: Treatment of hypoparathyroidism in adults.

Available dosage forms: 168 mcg/0.56 mL pen, 294 mcg/0.98 mL pen, 420 mcg/1.4 mL pen

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**: Hypoparathyroidism
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy:** 12 months
- ❒ **Prescriber Specialty**: Endocrinologist or in consultation with an endocrinologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - Provider attestation that patient is currently receiving conventional therapy, including active vitamin D (calcitriol) and elemental calcium, and that patient's disease cannot be adequately controlled on conventional therapy alone.
  - Current labs (within 60 days of request) have been submitted for the following:
    - Albumin-corrected serum calcium (must be > 7.8mg/dL to start therapy)
    - Serum vitamin D level (must be greater than or equal to 20 ng/mL to start therapy)
- ❒ Medication is prescribed at an FDA approved dose (maximum dose of 30mcg once daily).
- ❒ **Quantity**: 2 pens per 28 days
- ❒ **Age**: 18 years of age or older
- ❒ **Route of Administration**: subcutaneous

Criteria for continuation of therapy:

- ❒ Documentation of a recent albumin-corrected serum calcium in the lower-half of the normal reference range or just below the normal reference range (~8–9 mg/dL)
- ❒ **ONE** of the following:
  - Patient no longer requires active vitamin D or therapeutic doses of elemental calcium greater than 600 mg per day, **OR**
  - Patient has had a significant reduction in required dosages of active vitamin D or therapeutic doses of elemental calcium and is still actively titrating doses of Yorvipath
- ❒ Medication is prescribed at an FDA approved dose

ZORYVE / ROFLUMILAST

Drug Class: Dermatological - Antipsoriatic Agents Topical

FDA-approved uses:

- Zoryve 0.05% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age
- Zoryve 0.15% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for mild to moderate atopic dermatitis in adults and pediatric patients 6 years and older.
- Zoryve 0.3% Cream - A phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.
- Zoryve Foam - A phosphodiesterase 4 (PDE-4) inhibitor indicated for seborrheic dermatitis in patients 9 years of age and older.

Available dosage forms:

- Cream, 0.05% (0.5mg/gram)
- Cream, 0.15% (1.5mg/gram)
- Cream, 0.3% (3mg/gram)
- Foam, 0.3% (3mg/gram)

Coverage Criteria/Limitations for initial authorization:

- ❒ **Diagnoses**:
  - Plaque psoriasis (Zoryve 0.3% Cream)
  - Mild to moderate atopic dermatitis (Zoryve 0.15% Cream, Zoryve 0.05% Cream)
  - Seborrheic dermatitis (Zoryve Foam)
- ❒ **Duration of approval**:
  - **Initial authorization**: 6 months
  - **Continuation of Therapy**: for up to 12 months
- ❒ **Prescriber Specialty**: Prescribed by, or in consultation with, a dermatologist
- ❒ **Documentation Requirements** (e.g. Labs, Medical Record, Special Studies):
  - **All requests**
    - Prescribed to treat an FDA approved indication for topical Roflumilast **AND**
    - Prescribed volume is appropriate for treating the estimated body surface area affected or prescriber attests that the volume is necessary for up to a 34-day supply per fill. **AND**
    - Additional diagnosis-specific criteria below:
  - **For Plaque psoriasis**
    - Documented trial, failure, or intolerance to at least one high potency or very high potency topical steroid **AND**
    - Documented trial, failure, or intolerance to topical calcipotriene, calcitriol, tazarotene, or combination products containing prior stated ingredients **OR**
    - Clinical documentation as to why therapies listed above are not appropriate
  - **For Seborrheic dermatitis**
    - Documented trial, failure, or intolerance to at least one topical steroid **AND**
    - Documented trial, failure, or intolerance to at least one topical antifungal **OR**

        - Clinical documentation as to why prerequisite therapies listed above are not appropriate.

    - **For Mild to moderate atopic dermatitis**
        - Documented trial, failure, or intolerance to at least one topical steroid; **OR**
        - Clinical documentation as to why prerequisite therapies listed above are not appropriate.
- ❒ **Quantity**: See criteria
- ❒ **Age**:
    - 0.05% Cream ≥ 2 years old
    - 0.15% & 0.3% Cream ≥ 6 years old
    - Foam ≥ 9 years old
- ❒ **Route of Administration**: Topical

Criteria for continuation of therapy:

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