# Pharmacy Coverage Policy Manual

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## Preferred Drug List (PDL)

This contains coverage rules for medications including prior authorization criteria for medications billed by pharmacy point of sale systems and for HCPCS codes billed by a physician/clinic through an 837P transactions.

## Preferred Diabetes Supply List (PDSL)

This is a list of diabetes supplies billed by pharmacy point of sale systems.

## Prior Authorization Review Dates

Please see DUR Board found at https://ndmedicaid.acentra.com/

## Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence using the General Prior Authorization Form.
6. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
7. A trial will be considered a failure if a product was not effective at the maximum therapeutic dose with good compliance with most recent trial within the past 6 months, as evidenced by paid claims or pharmacy print outs. If unable to titrate dose to maximum therapeutic dose due to contraindication, intolerance, or lack of effect; trial requirements must be met with alternative preferred product(s) when applicable. Mitigation efforts must be provided, as applicable, with a request to bypass a trial for a preferred product(s) due to intolerance (subject to clinical review).
8. The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
9. Unless otherwise specified, the listing of a brand or generic name includes all legend formulations of that drug. OTC drugs are not covered unless specified. All drugs are pharmacy billed medications unless otherwise specified.
10. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Provider Administered Drug (Medical Billing) PA Form
    - Requested product is same active ingredient as preferred product: MedWatch Form
11. For pharmacy billed medication: please use the prior authorization website https://ndmedicaid.acentra.com/ to access PA forms, NDC Drug Lookup, quantity limits, and prior authorization information for all medications.
12. For medical billed medications: Please see the full list of medical drugs that require PA at https://www.hhs.nd.gov/human-services/medicaid/provider under the "Codes Requiring Service Authorization" tab at the bottom of the page.
13. All requirements outlined in the Pharmacy Provider Manual and any other federal or ND Medicaid manuals, policies, or guidance still apply. For example, when the PDL says a drug is covered without prior authorization, that does not imply that ND Medicaid will pay for that drug if someone has Medicare coverage.
14. If member is 65 years or older, on renal dialysis or has had a kidney transplant within the past 3 years, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

## Prior Authorization Updates

| Drug name | PA Status | Class |
|---|---|---|
| Alhemo | PA | Hemophilia |
| Alyftrek | PA | Cystic Fibrosis |
| Aqneursa | PA | Medications that cost over $3000 |
| Crenessity | PA | Medications that cost over $3000 |
| Hympavzi | PA | Hemophilia |
| Miplyffa | PA | Medications that cost over $3000 |
| Selarsdi | PA | Stelara Biosimilar |
| Steqeyma | PA | Stelara Biosimilar |
| Ustekinumab-ttwe | PA | Stelara Biosimilar |
| Yesintek | PA | Stelara Biosimilar |

## Version Changes

| Category | Change |
|---|---|
| Alpha-Mannosidosis | Criteria Updated |
| Chron's Disease | Criteria and Preferred Products Updated - Omvoh and Stelara biosimilars added |
| Glucose Rescue Medications | Preferred Products Updated |
| Insulin | Criteria and Preferred Products Updated - Insulin Vials Non-Preferred |
| Lysosomal Acid Lipase (LAL) Deficiency | Criteria Updated |
| Metabolic Dysfunction-Associated Steatohepatitis (MASH) | Criteria Updated |
| Metachromatic Leukodystrophy | Criteria Added |
| Mucopolysaccharidosis I (MPS I) | Criteria Updated |
| Mucopolysaccharidosis II (MPS II) – Hunter Syndrome | Criteria Updated |
| Mucopolysaccharidosis IVA (MPS IVA) – Morquio A syndrome | Criteria Updated |
| Mucopolysaccharidosis VII (MPS VII) – Sly Syndrome | Criteria Updated |
| Obstructive Sleep Apnea | Criteria Updated |
| Plaque Psoriasis | Criteria and Preferred Products Updated |
| Primary Biliary Cholangitis | Category Added |
| Ulcerative Colitis | Criteria and Preferred Products Updated - Stelara biosimilars added |
| X-linked Hypophosphatemia | Criteria Updated |

# General Policies

## Dispense as Written (DAW1)

*Member or prescriber preference is NOT criteria considered for approval.*

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- Request must meet one of the following (A or B):

A. Primary insurance requires a ND Medicaid non-preferred branded product.
B. All the following are met (1-4):
    1. The requested brand-name product must not have an authorized generic available.
    2. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product at maximum tolerated dose from each available manufacturer, as evidenced by paid claims or pharmacy print outs.
    3. Clinical justification is provided for the different clinical outcome expected for the requested brand and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    4. A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

## Generic Non-Preferred Requests

*Member or prescriber preference is NOT criteria considered for approval.*

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months (1 month for short-term request)*

- Request must meet one of the following (A, B, or C):
    A. Primary insurance requires a ND Medicaid non-preferred generic product.
    B. Pharmacy requests a short-term approval due to dose titration or supply issue.
    C. All the following are met (1-3):
        1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs.
        2. Clinical justification has been provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
        3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request.

## Medications that cost over $3000/month

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- Both of the following must be met:
    - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
    - The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.
- As applicable, confirmation of diagnosis must be provided as evidenced by serum markers or pathogenic gene variants amenable to treatment.
- Baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal have been submitted with request.

| CLINICAL PA REQUIRED |
| --- |
| ABECMA (idecabtagene vicleucel) – *Medical Billing* |
| ACTHAR (corticotropin) SELF-INJECTOR |
| ADSTILADRIN (nadofaragene firadenovec-vncg) – *Medical Billing* |
| AQNEURSA (levacetylleucine) |
| AUCATZYL (obecabtagene autoleucel) – *Medical Billing* |
| BLINCYTO (blinatumomab) – *Medical Billing* |
| BREYANZI (lisocabtagene maraleucel) – *Medical Billing* |
| CARVYKTI (ciltacabtagene autoleucel) – *Medical Billing* |
| CRENESSITY (crinecerfont) |
| CYSTADROPS (cysteamine) |
| CYSTARAN (cysteamine) |
| DANYELZA (naxitamab-gqgk) – *Medical Billing* |
| DAYBUE (trofinetide) |
| DOJOLVI (triheptanoin) |
| EPKINLY (epcoritamab-bysp) – *Medical Billing* |
| FIRDAPSE (amifampridine) |
| FOLOTYN (pralatrexate) – *Medical Billing* |
| FUROSCIX (furosemide) |
| FUROSCIX (furosemide) – *Medical Billing* |
| FYARRO (sirolimus protein-bound particles) – *Medical Billing* |
| GATTEX (teduglutide) |
| INCRELEX (mecasermin) |
| JOENJA (leniolisib) |
| KIMMTRAK (tebentafusp-tebn) – *Medical Billing* |
| KYMRIAH (tisagenlecleucel) – *Medical Billing* |
| Lanreotide |
| MIPLYFFA (arimoclomol) |
| MYCAPSSA (octreotide) |
| NULIBRY (fosdenopterin) |
| OXERVATE (cenegermin-bkbj) |
| PYRUKYND (mitapivat) |
| REZUROCK (belumosudil) |
| SKYCLARYS (omaveloxolone) |
| SPEVIGO (spesolimab-sbzo) |
| SOHONOS (palovarotene) |
| TAVNEOS (avacopan) |
| TECARTUS (brexucabtagene autoleucel) – *Medical Billing* |
| TECVAYLI (Inj teclistamab cqyv 0.5 mg) – *Medical Billing* |
| TIVDAK (tisotumab vedotin-tftv) – *Medical Billing* |
| VEOPOZ (pozelimab) – *Medical Billing* |
| VIJOICE (alpelisib) |
| WELIREG (belzutifan) |
| XENPOZYME (olipudase alfa) – *Medical Billing* |
| XOLREMDI (mavorixafor) |
| YESCARTA (axicabtagene ciloleucel) – *Medical Billing* |
| ZOKINVY (lonafamib) |
| ZYNLONTA (loncastuximab tesirine-lpyl) – *Medical Billing* |

## Non-Solid Dosage Forms

### *Electronic Age Verification*

- Non-Solid Dosage Forms that do not require prior authorization for clinical criteria will reject at the point of sale for members 10 years and older to verify they meet Non-Solid Dosage Form prior authorization criteria.

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 3 years (1 month for short-term restriction)*

- One of the following criteria is met:
  - The member has a feeding tube placed and the medication is not available in a dosage form that can be crushed or poured into the tube.
  - The member does not have a feeding tube placement but one of the following apply:
    - Swallow study documentation has been submitted showing inability to swallow.
    - Permanent disability of swallowing solid dosage forms
    - Short-term restriction (e.g., mouth surgery)

## Renewal Requests

### *Prior Authorization Criteria*

*Renewal Criteria*

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional renewal criteria may apply as indicated under specific category.
- One of the following must be met (1 or 2):
  1. *Approval Duration: regular renewal approval duration or 1 year*
     - The member was at least 80% adherent to medication, excluding any claim gaps due to hospitalization or eligibility.
  2. *Approval Duration: 3 months*
     - All the following must be met -
       - Clinical justification must be provided for the non-adherence.
       - A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.
       - Clinical justification must be provided to continue treatment and how efficacy is assessed despite non-adherence.

# Allergy/Immunology

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time.

# Chronic Idiopathic Urticaria

## Biologic Agents

| CLINICAL PA REQUIRED |
|---|
| XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR |
| XOLAIR (omalizumab) VIALS – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 3 months*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have failed a 30-day trial of a dose of fourfold normal dosing of second-generation $H_1$ antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in addition to the following, as evidenced by paid claims or pharmacy printouts:
    - Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
    - Histamine $H_2$-receptor (e.g., ranitidine, famotidine, nizatidine, cimetidine)

**References**


1. Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
2. Schaefer P. Acute and Chronic Urticaria: Evaluation and Treatment. Am Fam Physician. 2017 Jun 1;95(11):717-724. PMID: 28671445
3. Zuberbier, Torsten, et al. "The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria." *Allergy* 77.3 (2022): 734-766.


# Chronic Rhinosinusitis with Nasal Polyps

## Steroids – Nasal Spray

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fluticasone | XHANCE (fluticasone) |

*Initial Criteria - Approval Duration: 12 months*

- Xhance (fluticasone) Only: See Preferred Dosage Form criteria

## Biologics

### *Anti-IL-4/13 biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DUPIXENT (dupilumab) | |

### *Anti-IL-5 biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR |
| | NUCALA (mepolizumab) VIAL – *Medical Billing* |

### *Eosinophil-directed biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR | |
| XOLAIR (omalizumab) VIAL – *Medical Billing* | |

### *Prior Authorization Criteria*

Prior Authorization Form - Nasal Polyps

*Initial Criteria - Approval Duration: 3 months*

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have failed a 12-week trial of intranasal corticosteroids, as evidenced by paid claims or pharmacy printouts.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year, as evidenced by paid claims or pharmacy printouts.
- The member must have bilateral polyps confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

*Non-Preferred Agent Criteria:*

- The member must have failed a 90-day trial with each preferred agent, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria - Approval Duration: 12 months*

- The member must have received a therapeutic response as evidenced by a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

**References:**

1. Rank, Matthew A., et al. "The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis." *Journal of Allergy and Clinical Immunology* 151.2 (2023): 386-398.

## Cytokine Release Syndrome

### Biologic Agents

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See “Biosimilar Agents” | |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 4 doses*

- The member must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia.

**References**

- Porter DL, Maloney DG. Cytokine Release Syndrome. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2024

# Deficiency of IL-A Receptor Antagonists (DIRA)

## Biologic Agents

*Interleukin (IL) -1 Receptor Inhibitors*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KINERET (anakinra) | ARCALYST (rilonacept) |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The member must have failed a 3-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

**References**


- Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023


# Eosinophilic Granulomatosis with Polyangiitis (EGPA)

## Biologic Agents

*Anti-B-cell Therapy*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab – See "Biosimilar Agents" | |

*Anti-IL-5 Biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FASENRA (benralizumab) | NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR |
| | NUCALA (mepolizumab) VIAL – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a pulmonologist, rheumatologist, or allergy/immunology specialist.
- The member must not have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)
- The member must have received at least 4 weeks of an oral corticosteroid dose ≥ 7.5 mg/day to control relapsing or refractory disease.
- The member must have asthmatic manifestations on a combination of high doses of inhaled glucocorticoids and long acting β2-agonist.
- The member must have blood eosinophil count of ≥ 1000 cells/mcL and/or ≥10 percent of leukocytes within the previous 6 weeks.

*Non-Preferred Agents Criteria*

- The member must have failed a 3-month trial of Fasenra, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria - Approval Duration: 12 months (one time renewal except in history of multiple relapses)*
- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, subject to clinical review.

*Relapse is defined as active vasculitis, active asthma symptoms, active nasal or sinus disease requiring the use of glucocorticoids or immunosuppressants.

**References**


1. Chung SA, Langford CA, Maz M, Abril A, Gorelik M, Guyatt G, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody–associated vasculitis. *Arthritis Care Res (Hoboken)* 2021; 73: 1088– 1105.
2. Jennette, J.C., Falk, R.J., Bacon, P.A., Basu, N., Cid, M.C., Ferrario, F., Flores-Suarez, L.F., Gross, W.L., Guillevin, L., Hagen, E.C., Hoffman, G.S., Jayne, D.R., Kallenberg, C.G.M., Lamprecht, P., Langford, C.A., Luqmani, R.A., Mahr, A.D., Matteson, E.L., Merkel, P.A., Ozen, S., Pusey, C.D., Rasmussen, N., Rees, A.J., Scott, D.G.I., Specks, U., Stone, J.H., Takahashi, K. and Watts, R.A. (2013), 2012 Revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. Arthritis & Rheumatism, 65: 1-11. https://doi.org/10.1002/art.37715
3. King, Jr. TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
4. Emmi, Giacomo, et al. "Evidence-Based Guideline for the diagnosis and management of eosinophilic granulomatosis with polyangiitis." *Nature reviews Rheumatology* 19.6 (2023): 378-393.


## Food Allergy

### *Eosinophil-directed biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR | |
| XOLAIR (omalizumab) VIAL – *Medical Billing* | |

### *Oral Immunotherapy*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| PALFORZIA (peanut allergen powder) | |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*
- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member has one of the following (A, B, or C):
  - A. The member has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization.
  - B. Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.
  - C. The member has all the following:
  - o History of urticaria, angioedemia, or wheeze
  - o Skin prick wheal of at least 3 mm or positive IgE test as determined by allergist/immunologist (at least 0.35 kUA/L for Palforzia and at least 30 IU/mL for Xolair)
  - o Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

*Renewal Criteria (Palforzia Only) - Approval Duration: 6 months for continued up-titration or 12 months for maintenance the 300 mg dose.*

- The member must have been adherent with therapy (last 6 fills must have been on time).
- One of the following must be met (A or B)
    A. The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily) OR
    B. An up-titration plan to a final dose of 300 mg daily by week 40 and this is a first request for an up-titration renewal.

# Hypereosinophilic Syndrome (HES)

## Biologic Agents

| CLINICAL PA REQUIRED |
|---|
| NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR |
| NUCALA (mepolizumab) VIAL – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a hematologist, or allergy/immunology specialist.
- The member must be FIP1L1-PDGFRα kinase-negative.
- The member must have experienced at least 2 HES flares within the past 12 months despite a 3-month trial with oral corticosteroid ≥ 7.5 mg/day, as evidenced by paid claims or pharmacy printouts.
- The member must have a blood eosinophil count of 1000 cells/mcL or higher.

*Renewal Criteria - Approval Duration: 12 months*

- The member must have experienced and maintained clinical benefit (e.g., reduction in flares, decreased blood eosinophilic count, reduction in corticosteroid dose or steroid sparing therapy) since starting treatment with the requested medication, subject to clinical review.

# Gout

## Flare Treatment

## Oral agents

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| colchicine tablet | colchicine capsule |
| NSAIDs | GLOPERBA (colchicine) ORAL SOLUTION |
| Oral Corticosteroids | MITIGARE (colchicine) CAPSULE |

### *Prior Authorization Criteria*

- See applicable Preferred Dosage Form or Non-Solid Oral Dosage Form criteria.

## Biologic Agents

*Interleukin (IL) -1 Receptor Inhibitors*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| ILARIS (canakinumab) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member is concurrently taking a medication for prophylaxis of gout flares
- The member must have failed a 7-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - colchicine
  - NSAIDs
  - corticosteroids

# Urate Lowering Therapy

## Uricosuric Drugs

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| probenecid-colchicine tablets | |
| probenecid tablets | |

## Xanthine Oxidase Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | AZASAN (azathioprine) |
| allopurinol 100 mg, 300 mg tablet | allopurinol 200 mg tablet |
| | azathioprine 75 mg, 100 mg tablet |
| | ++febuxostat |
| | IMURAN (azathioprine) |
| | ++ULORIC (febuxostat) TABLET |
| | ZYLOPRIM (allopurinol) TABLET |

++Clinically Non-Preferred: In clinical trials, febuxostat had a higher incidence of thromboembolic cardiovascular events and hepatic abnormalities compared to allopurinol.

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

The member must meet one of the following criteria:

- The member must have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts
- The member is HLA-B*5801 positive

## Uricase

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| KRYSTEXXA (pegloticase) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member must have failed a 3-month trial of two of the following, as evidenced by paid claims or pharmacy printouts:
  - allopurinol
  - febuxostat
  - allopurinol or febuxostat in combination with probenecid
- The failure of previous trials must be documented by both of the following (A and B):
  - A. A. Serum uric acid level ≥ 6 mg/dL within the past month
  - B. One of the following (i, ii, or iii):
    - i. At least 3 gout flares in the previous 18 months that were inadequately controlled.
    - ii. At least 1 gouty tophus
    - iii. Chronic gouty arthropathy/arthritis

*Renewal Criteria - Approval Duration: 12 months*

- The member is not experiencing infusion reactions.
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including both of the following:
  - Serum uric acid level < 6 mg/dL within the past month
  - Decrease in gout flares or nonrevolving tophaceous deposits

# Hereditary Angioedema (HAE)

## Acute Attack

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Icatibant | BERINERT (plasma derived C1 Esterase Inhibitor) |
| | BERINERT (plasma derived C1 Esterase Inhibitor) – *Medical Billing* |
| | FIRAZYR (icatibant) |
| | KALBITOR (ecallantide) – *Medical Billing* |
| | RUCONEST (recombinant C1 Esterase Inhibitor) |
| | RUCONEST (recombinant C1 Esterase Inhibitor) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.

*Non-Preferred Agent Criteria:*

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.
    - Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.
    - Ruconest Only: The member must have a contraindication to or failed a trial of Berinert, as evidenced by paid claims or pharmacy printouts.

## Prophylaxis

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HAEGARDA (plasma derived C1 Esterase Inhibitor) | CINRYZE (plasma derived C1 Esterase Inhibitor) |
| TAKHZYRO (lanadelumab-flyo) | ORLADEYO (berotrlastat) |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
    - The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
    - The member is using short-term prophylaxis for one of the following:
        - a procedure related to pregnancy
        - oral cavity or invasive procedures
        - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
        - Estrogen treatment is required, and member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

*Non-Preferred Agent Criteria:*

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

### *Quantity Override Request*

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

**References**


1. Busse, Paula J., et al. "US HAEA medical advisory board 2020 guidelines for the management of hereditary angioedema." *The Journal of Allergy and Clinical Immunology: In Practice* 9.1 (2021): 132-150.

## Immune Globulins

*IM*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| GAMASTAN (immune globul G (IgG)/glycine) | |
| GAMASTAN (immune globul G (IgG)/glycine) – *Medical Billing* | |

*IVIG*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BIVIGAM (human immunoglobulin G) | ALYGLO (human immunoglobulin G - stwk) |
| BIVIGAM (human immunoglobulin G) – *Medical Billing* | ALYGLO (human immunoglobulin G - stwk) – *Medical Billing* |
| GAMMAGARD S-D (human immunoglobulin G) | ASCENIV (human immune globulin G- slra) |
| GAMMAPLEX (human immunoglobulin G) | ASCENIV (human immune globulin G- slra) – *Medical Billing* |
| GAMMAPLEX (human immunoglobulin G) – *Medical Billing* | PANZYGA (human immune globulin G- ifas) |
| OCTAGAM (human immunoglobulin G) | PANZYGA (human immune globulin G - ifas) – *Medical Billing* |
| OCTAGAM (human immunoglobulin G) – *Medical Billing* | |
| PRIVIGEN (human immunoglobulin G) | |
| PRIVIGEN (human immunoglobulin G) – *Medical Billing* | |

*IVIG/SCIG*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| GAMMAGARD LIQUID (human immunoglobulin gamma) | |
| GAMMAKED (human immunoglobulin gamma) | |
| GAMMAKED (human immunoglobulin gamma) – *Medical Billing* | |
| GAMUNEX-C (human immunoglobulin gamma) | |
| GAMUNEX-C (human immunoglobulin gamma) – *Medical Billing* | |

*SCIG*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CUTAQUIG (human immune globulin G - hipp) | CUVITRU (human immunoglobulin gamma) |
| CUTAQUIG (human immune globulin G - hipp) – *Medical Billing* | CUVITRU (human immunoglobulin gamma) – *Medical Billing* |
| HIZENTRA (human immunoglobulin gamma) | HYQVIA (human immune globulin G and hyaluronidase) |
| HIZENTRA (human immunoglobulin gamma) – *Medical Billing* | HYQVIA (human immune globulin G and hyaluronidase) – *Medical Billing* |
| XEMBIFY (immune globulin,gamma(IgG)klhw) | |

| | |
|---|---|
| XEMBIFY (immune globulin,gamma(IgG)klhw) – *Medical Billing* | |

### *Electronic Diagnosis and Quantity Verification*

- For medical billing only: the following Local Coverage Determination applies to applicable preferred and non-preferred agents: Article - Billing and Coding: Immune Globulin Intravenous (IVIg) (A57187) (cms.gov)

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- The member must meet one of the following criteria:
  - The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts.
  - The member is stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

## Steroids – Nasal Spray

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DYMISTA (azelastine-fluticasone) – *Brand Required* | azelastine-fluticasone |
| Fluticasone | BECONASE AQ (beclomethasone) |
| mometasone – labeler 60605 | flunisolide |
| OMNARIS (ciclesonide) | mometasone – labeler 65152 |
| QNASL (beclomethasone) | QNASL CHILDREN (beclomethasone) |
| ZETONNA (ciclesonide) | RYALTRIS (olopatadine/mometasone) |
| | XHANCE (fluticasone) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Xhance (fluticasone) Only: See Preferred Dosage Form Criteria

# Cardiology

### *Therapeutic Duplication*

- One Strength of one medication is allowed at a time
  - Exceptions:
    - carvedilol IR 25 mg allowed with all other strengths
    - warfarin strengths are allowed together
    - prazosin strengths are allowed together
- Medication classes not payable together:
  - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
  - sildenafil, tadalafil, Adempas, nitrates are not allowed with each other.
  - carvedilol and labetalol are not allowed with other non-selective alpha blockers (Alfuzosin ER, doxazosin, prazosin, and terazosin)

    - carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity
  - tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
    - tizanidine is also an alpha 2 agonist
  - clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
    - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
    - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

## Alpha and/or Beta Blockers Therapeutic Duplication – Override Request

Overrides may be available for alpha and/or beta blockers for use within the cardiac or nephrology specialties if they have a difference in mechanism of action (e.g., non-selective or selective beta blocking activity, with or without alpha-1 blocker activity). Please request an override by calling provider relations at 1-800-755-2604.

- The prescribers of each medication must be aware of each other.
- The requested medications must be prescribed by, or in consult with, a cardiologist or nephrologist.

# Anticoagulants

## Anticoagulants - Direct Oral Anticoagulants (DOACs)

*Solid oral dosage forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ELIQUIS (apixaban) | dabigatran capsule |
| PRADAXA (dabigatran) capsule – *Brand Required* | SAVAYSA (edoxaban) |
| XARELTO (rivaroxaban) | |

*Non-solid oral dosage forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XARELTO (rivaroxaban) SUSPENSION | PRADAXA (dabigatran) PELLET |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent and warfarin, as evidenced by paid claims or pharmacy printouts.

### Reduction of Risk of Major Cardiovascular Events in Chronic CAD or PAD

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XARELTO (rivaroxaban) 2.5 mg | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Xarelto 2.5 mg: The diagnosis must be provided with the request.

## Anticoagulants - Injectables

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Enoxaparin | ARIXTRA (fondaparinux) |
| | fondaparinux – *No PA required for HIT diagnosis** |
| | FRAGMIN (dalteparin) |
| | LOVENOX (enoxaparin) |

### *Electronic Diagnosis Verification*

- Fondaparinux: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale*

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.

## Calcium Channel Blockers

### *Non-solid oral dosage forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NORLIQVA (amlodipine) SOLUTION | KATERZIA (amlodipine) SUSPENSION |
| NYMALIZE (nimodipine) SOLUTION | nimodipine solution |

### *Electronic Diagnosis Verification*

- Nymalize: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Solid oral dosage forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Amlodipine | ADALAT CC (nifedipine) |
| CARTIA XR (diltiazem) | CALAN SR (verapamil) |
| Diltiazem | CARDIZEM (diltiazem) |
| diltiazem ER | CARDIZEM CD (diltiazem) |
| DILT-XR (diltiazem) | levamlodipine |
| felodipine ER | nisoldipine ER 20 mg, 30 mg, 40 mg |
| Isradipine | NORVASC (amlodipine) |
| MATZIM LA (diltiazem) ER | PROCARDIA XL (nifedipine) |
| Nicardipine | SULAR ER (nisoldipine) |
| Nifedipine | TIAZAC (diltiazem) |
| nifedipine ER | TIAZAC ER (diltiazem) |
| Nimodipine | verapamil ER PM |
| nisoldipine ER 8.5 mg, 17 mg, 25.5 mg, 34 mg | VERELAN (verapamil) |
| TAZTIA XT (diltiazem) | VERELAN PM (verapamil) |
| TIADYLT ER (diltiazem) | |
| Verapamil | |
| verapamil ER | |

*Prior Authorization Criteria*

- Katerzia, Verapamil ER PM, Nisoldipine ER 20 mg, 30 mg, 40 mg, levamlopidine:
  - See Preferred Dosage Form criteria

# Diuretics

## Diuretics – Loop

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| furosemide | ethacrynic acid |
| bumetanide | |
| torsemide | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Ethacrynic acid: One of the following must be met:
  1. The member must have a documented sulfa allergy.
  2. The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

## Diuretics – Potassium Sparing / Sodium channel blocker

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amiloride | triamterene |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy print outs.

## Diuretics – Potassium Sparing / Aldosterone Antagonist

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amiloride | ALDACTONE (spironolactone) TABLET |
| eplerenone | CAROSPIR (spironolactone) SUSPENSION |
| spironolactone suspension | INSPRA (eplerenone) |
| spironolactone tablet | |

# Heart Failure

## Solid Dosage Forms

*First Line Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred* | dapagliflozin |

| | |
|---|---|
| ARBs (angiotensin receptor blockers) – *all oral agents preferred* | INPEFA (sotagliflozin) |
| Beta blockers – *all oral agents preferred* | SAMSCA (tolvaptan) |
| Diuretics | sacubitril/valsartan |
| ENTRESTO (sacubitril/valsartan) – *Brand Required* | tolvaptan |
| FARXIGA (dapagliflozin) – *Brand Required* | |
| JARDIANCE (empagliflozin) | |

### *Second Line Agents*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ivabradine | CORLANOR (ivabradine) |
| VERQUVO (vericiguat) | |

## Non-Solid Dosage Forms

### *First Line Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| enalapril oral solution | ENTRESTO (sacubitril/valsartan) SPRINKLE |
| | EPANED (enalapril) SOLUTION |

### *Electronic Diagnosis Verification*

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Electronic Duration Verification:*

- tolvaptan is payable for 30 days every year.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3-month trial of enalapril, as evidenced by paid claims or pharmacy printouts.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.
  - Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)

- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist
  - The member is experiencing sodium levels less than 125 mEq/L despite a 30-day trial of an ACE inhibitor or ARB, as evidenced by paid claims or pharmacy printouts..
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

## Hypertrophic Cardiomyopathy

| CLINICAL PA REQUIRED |
|---|
| CAMZYOS (mavacamten) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated therapy with each of the following:
  - Non-dihydropyridine calcium channel blocker
  - beta blocker

*Renewal Criteria – Approval Duration: 12 months*

- The member has one of the following:
  - an improved $pVO_2$ by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of $pVO_2$ by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

**References**


1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
2. Desai, Milind Y., et al. “Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results From the VALOR-HCM randomized clinical trial.” JAMA cardiology 8.10 (2023): 968-977.


## Inappropriate Sinus Tachycardia

| CLINICAL PA REQUIRED |
|---|
| CORLANOR (ivabradine) |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The diagnosis must be provided on the request.

## Lipid-Lowering Agents

### *ACL (ATP Citrate Lyase) Inhibitors*

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NEXLETOL (bempedioc acid) | |
| NEXLIZET (bempedoic acid and ezetimibe) | |

### *Electronic Step Therapy Required*

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

### *Cholesterol Absorption Inhibitor – 2-Azetidinone*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Ezetimibe | ZETIA (ezetimibe) |

### *Eicosapentaenoic acid (ESA) Ethyl Ester*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| VASCEPA (icosapent ethyl) – *Brand Required* | icosapent ethyl |

### *Fenofibrate*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg | ANTARA (fenofibrate, micronized) |
| fenofibrate, nanocrystallized | fenofibrate capsules 50 mg, 150 mg |
| fenofibrate tablets 54 mg, 160 mg | fenofibrate, micronized 90 mg, 130 mg |
| fenofibric acid DR 45 mg, 135 mg | fenofibrate tablets 40 mg, 120 mg |
| | fenofibric acid 105 mg |
| | FENOGLIDE (fenofibrate) |
| | LIPOFEN (fenofibrate) |
| | TRICOR (fenofibrate, nanocrystalized) |
| | TRIGLIDE (fenofibrate) |
| | TRILIPIX (fenofibric acid) |

### *Prior Authorization Criteria*

- See Preferred Dosage Form criteria

### *MTP (Microsomal Triglyceride Transfer Protein) Inhibitor*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | JUXTAPID (lomitapide) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

### *PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors*

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| REPATHA PUSHTRONEX (evolocumab) | PRALUENT PEN (alirocumab) |
| REPATHA SURECLICK (evolocumab) | |
| REPATHA SYRINGE (evolocumab) | |

### *Underutilization*

- Praluent and Repatha must be used adherently and will reject on point of sale for late fill.

### *Electronic Step Therapy Required*

- Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must have failed a 90-day trial of the preferred PCSK9 inhibitor agent, as evidenced by paid claims or pharmacy printouts

*Renewal Criteria – Approval Duration: 12 months*

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

### *Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors))*

Solid Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amlodipine/atorvastatin | ALTROPREV (lovastatin) |
| Atorvastatin | CADUET (amlodipine/atorvastatin) |
| ezetimibe/simvastatin | CRESTOR (rosuvastatin) |
| Fluvastatin | fluvastatin ER |
| Lovastatin | LESCOL XL (fluvastatin ER) |
| Pravastatin | LIPITOR (atorvastatin) |
| Rosuvastatin | LIVALO (pitavastatin) |
| Simvastatin | pitavastatin |
| | PRAVACHOL (pravastatin) |
| | VYTORIN (ezetimibe/simvastatin) |
| | ZOCOR (simvastatin) |
| | ZYPITAMAG (pitavastatin) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin, as evidenced by paid claims or pharmacy printouts..
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EZALLOR SPRINKLE (rosuvastatin) | ATORVALIQ (atorvastatin) SOLUTION |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Non-Solid Dosage Form criteria

*Non-Preferred Agent Criteria*

- The member has an LDL-C level greater than 100 mg/dL despite a 90-day trial with Ezallor Sprinkle, as evidenced by paid claims or pharmacy printouts..

*Renewal Criteria – Approval Duration: 12 months*

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

### *Angiopoietin-like 3 (ANGPTL3) Inhibitor*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | EVKEEZA (evinacumab-dgnb) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- One of the following must be met:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):
    - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

- Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

*Renewal Criteria – Approval Duration: 12 months*

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

### *siRNA (small interfering RNA) therapy*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | LEQVIO (inclisiran) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - PCSK9 inhibitor combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

*Renewal Criteria – Approval Duration: 12 months*

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts.

## Platelet Aggregation Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Aspirin | clopidogrel 300 mg |
| aspirin/dipyridamole ER | EFFIENT (prasugrel) |
| BRILINTA (ticagrelor) | PLAVIX (clopidogrel) |
| clopidogrel 75 mg | ZONTIVITY (vorapaxar) |
| Dipyridamole | |
| Prasugrel | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed 30-day trials of at least 3 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

## Pulmonary Hypertension

### Activin Signaling Inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| WINREVAIR (sotatercept-csrk) | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- The member must currently be on a dual therapy combination regimen.

*Renewal Criteria – Approval Duration: 12 months*

- The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
  - 6MWT (≤ 15% decline)
  - WHO functional class

## Endothelin Receptor Antagonists

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Ambrisentan | LETAIRIS (ambrisentan) |
| Bosentan | OPSUMIT (macitentan) |
| TRACLEER (bosentan) SUSPENSION | OPSYNVI (macitentan/tadalafil) |
| | TRACLEER (bosentan) TABLETS |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of ambrisentan, as evidenced by paid claims or pharmacy printouts.

## PDE-5 Inhibitors

### *Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALYQ (tadalafil) | ADCIRCA (tadalafil) TABLET |
| sildenafil tablet | OPSYNVI (macitentan/tadalafil) |
| tadalafil tablet | REVATIO (sildenafil) TABLET |

### *Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| sildenafil suspension – all other labelers | LIQREV (sildenafil) SUSPENSION |
| | REVATIO (sildenafil) SUSPENSION |
| | sildenafil suspension – labeler 59762 |
| | TADLIQ (tadalafil) SUSPENSION |

### *Electronic Age Verification*

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 18 years old.
- Sildenafil suspension: Prior authorization is not required for ages less than 9 years old.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The request must include medical documentation (i.e., clinical notes) to verify diagnosis.

*Non-Preferred Agents Criteria*

- The member must have failed a 30-day trial of a preferred product, as evidenced by paid claims or pharmacy printouts.
- Liqrev Only: See Preferred Dosage Form criteria

## Prostacyclins

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Epoprostenol | |
| FLOLAN (epoprostenol) | |
| ORENITRAM ER (treprostinil) TABLET | |
| REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred* | |
| treprostinil injection – *Generic Co-Preferred* | |
| TYVASO (treprostinil) DPI | |
| TYVASO (treprostinil) INHALATION | |
| UPTRAVI (selexipag) TABLET | |
| UPTRAVI (selexipag) VIAL | |
| VELETRI (epoprostenol) | |
| VENTAVIS (iloprost) INHALATION | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

## Soluble Guanylate Cyclase Stimulators

| NO PA REQUIRED |
|---|
| ADEMPAS (riociguat) |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

**References:**


1. Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)." *European heart journal* 43.38 (2022): 3618-3731.


# Reduction of Major Adverse Cardiovascular Events (MACE)

## Oral Agents

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| See Lipid-Lowering Agents | |

| | |
|---|---|
| See Platelet Aggregation Inhibitors | |

## Injectable Agents

### *PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors*

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| PRALUENT PEN (alirocumab) | |
| REPATHA PUSHTRONEX (evolocumab) | |
| REPATHA SURECLICK (evolocumab) | |
| REPATHA SYRINGE (evolocumab) | |

#### *Electronic Step Therapy Required*

- Praluent and Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Praluent and Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

### *GLP-1 Agonists*

| CLINICAL PA REQUIRED |
|---|
| WEGOVY (semaglutide) |

#### *Prior Authorization Criteria*

For reduction of MACE in members with diabetes, please see diabetes category for criteria on indicated agents.

*Initial Criteria – Approval Duration: 12 months*

- The member is ages of ≥ 55 and < 75.
- The member does not have diabetes, as evidenced by A1c within normal range without diabetes medication.
- The member has an initial BMI of ≥ 27 kg/m$^2$ and < 35 kg/m$^2$
- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- If the member qualifies for Wegovy, a dose escalation to 2mg of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized (2.4mg is the only strength indicated for reduction of MACE)

# Dermatology

## Acne

### *Electronic Age Verification*

- The member must be between 12 and 35 years of age for treatment of diagnosis of acne.

## Adapalene

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adapalene cream | CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL |
| adapalene gel | |
| adapalene gel with pump | |
| adapalene/benzoyl peroxide 0.1%-2.5% | |
| adapalene/benzoyl peroxide 0.3%-2.5% | |

### *Therapeutic Duplication*

- One strength of one benzoyl peroxide containing medication is allowed at a time.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form criteria

## Androgen Receptor Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | WINLEVI (clascoterone) CREAM |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Topical antibiotics (erythromycin, clindamycin, minocycline, or dapsone) in combination with benzoyl peroxide
    - Topical retinoids in combination with benzoyl peroxide

## Clindamycin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| clindamycin capsule | CLEOCIN T (clindamycin) GEL |
| clindamycin gel | CLEOCIN T (clindamycin) LOTION |
| clindamycin lotion | CLEOCIN T (clindamycin) PLEDGETS |
| | CLINDACIN (clindamycin) FOAM |
| clindamycin solution | CLINDACIN P (clindamycin) PLEDGETS |

| | |
|---|---|
| ZIANA (clindamycin-tretinoin 1.2%-0.025%) – *Brand Required* | CLINDACIN ETZ (clindamycin) PLEDGETS |
| | CLINDAGEL (clindamycin) GEL DAILY |
| | clindamycin gel daily |
| | clindamycin foam |
| | clindamycin pledgets |
| | clindamycin-tretinoin 1.2%-0.025% |
| | EVOCLIN (clindamycin) FOAM |

## Clindamycin-Benzoyl Peroxide

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| clindamycin-benzoyl peroxide 1.2%-2.5% | ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5% |
| clindamycin-benzoyl peroxide 1%-5% with pump | BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5% |
| clindamycin-benzyl peroxide 1.2%-5% | BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5% |
| clindamycin/benzoyl peroxide 1%-5% without pump | CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL |
| ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75% - *Brand Required* | clindamycin/benzoyl peroxide 1.2%-3.75% |
| | NEUAC (clindamycin/benzoyl peroxide) 1.2%-5% |

### *Therapeutic Duplication*

- One strength of one benzoyl peroxide containing medication is allowed at a time.

## Retinoid

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALTRENO (tretinoin) LOTION | ATRALIN (tretinoin) 0.05% GEL |
| RENOVA WITHOUT PUMP (tretinoin/emollient base) | ARAZLO (tazarotene) 0.045% LOTION |
| RENOVA WITH PUMP (tretinoin/emollient base) | clindamycin-tretinoin 1.2%-0.025% |
| RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required* | FABIOR (tazarotene) 0.1% FOAM |
| RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP – *Brand Required* | RETIN-A (tretinoin) CREAM |
| tazarotene 0.1% cream | RETIN-A (tretinoin) GEL |
| tretinoin cream | RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.06%, 0.08% |
| tretinoin gel | tazarotene 0.05% cream |
| ZIANA (clindamycin-tretinoin 1.2%-0.025%) – *Brand Required* | tazarotene 0.1% foam |
| | tazarotene gel |
| | tretinoin microsphere gel with pump 0.04%, 0.1% |
| | tretinoin microsphere gel without pump |

### *Therapeutic Duplication*

- One strength of one retinoid medication is allowed at a time.
- One strength of one benzoyl peroxide containing medication is allowed at a time.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- See Preferred Dosage Form criteria

## Tetracyclines

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| doxycycline hyclate capsule | demeclocycline |
| doxycycline hyclate tablet 20 mg, 100 mg | DORYX (doxycycline hyclate) TABLET DR |
| doxycycline monohydrate 25 mg/5 mL suspension | DORYX MPC (doxycycline hyclate) TABLET DR |
| doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg | doxycycline monohydrate capsule 75 mg, 150 mg |
| doxycycline monohydrate capsule 50 mg, 100 mg | doxycycline hyclate tablet 50 mg, 75 mg, 150 mg |
| minocycline capsule | doxycycline monohydrate tablet 150 mg |
| tetracycline | doxycycline hyclate tablet DR |
| | MINOCIN (minocycline) CAPSULE |
| | minocycline tablet |
| | minocycline tablet ER |
| | MINOLIRA ER (minocycline) TABLET |
| | MORGIDOX (doxycycline hyclate) CAPSULE |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- See Preferred Dosage Form criteria

## Sulfonamide

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1% | ACZONE (dapsone) GEL WITH PUMP 7.5% |
| BP CLEANSING WASH (sulfacetamide sodium/sulfur/urea) 10%-4%-10% | BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER |
| dapsone gel pump 7.5% | KLARON (sulfacetamide sodium) |
| dapsone gel without pump 5% | SSS 10-5 (sulfacetamide) CLEANSER |
| sulfacetamide 10% cleansing gel | SSS 10-5 (sulfacetamide) FOAM |
| sulfacetamide 10% lotion | sodium sulfacetamide/sulfur pads 10%-4% |
| sulfacetamide 10% suspension | sodium sulfacetamide/sulfur cream 10%-2% |
| sulfacetamide 10% wash | SUMADAN (sodium sulfacetamide/sulfur) WASH 9%-4.5% |
| sodium sulfacetamide/sulfur cleanser 10%-5% (W/W) | SUMAXIN (sodium sulfacetamide/sulfur) WASH 9%-4% |
| sodium sulfacetamide/sulfur cleanser 9%-4% | SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4% |

| | |
|---|---|
| sodium sulfacetamide/sulfur cleanser 9%-4.5% | SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4% |
| sodium sulfacetamide/sulfur cleanser 9.8% -4.8% | ZMA CLEAR (sulfacetamide sodium/sulfur) SUSPENSION 9%-4.5% |
| sodium sulfacetamide/sulfur cleanser 10%-2% | |
| sodium sulfacetamide/sulfur cleanser 10%-5%-10% | |
| sodium sulfacetamide/sulfur cream 10%-5% (W/W) | |
| sodium sulfacetamide/sulfur suspension 8%-4% | |
| SUMAXIN (sodium sulfacetamide/sulfur) CLEANSER 9%-4% | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form criteria

## Actinic Keratosis

### Fluorouracil

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CARAC (fluorouracil) 0.5% CREAM – *Brand Required* | EFUDEX (fluorouracil) 5% CREAM |
| fluorouracil 5% cream | fluorouracil 0.5% cream |
| fluorouracil 2% solution | |
| fluorouracil 5% solution | |

### Imiquimod

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| imiquimod 5% cream packet | imiquimod 3.75% cream packet |
| ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required* | imiquimod 3.75% cream pump |
| | ZYCLARA (imiquimod) 3.75% CREAM PACKET |
| | ZYCLARA (imiquimod) 2.5% CREAM PUMP |

### Diclofenac

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| diclofenac 3% sodium gel | |

### *Electronic Diagnosis Verification*

- Diclofenac 3% sodium gel: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, see Preferred Dosage Form criteria

# Antifungals – Topical

*Cream*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| butenafine cream | CICLODAN (ciclopirox) CREAM |
| ciclopirox cream | ERTACZO (sertraconazole) CREAM |
| clotrimazole cream | EXELDERM (sulconazole) CREAM |
| econazole cream | LOPROX (ciclopirox) CREAM |
| ketoconazole cream | luliconazole cream |
| miconazole cream | LUZU (luliconazole) CREAM |
| NAFTIN (naftifine) CREAM | MENTAX (butenafine) CREAM |
| nystatin cream | naftifine cream |
| nystatin – triamcinolone cream | oxiconazole cream |
| | sulconazole cream |

*Foam*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ketoconazole foam | EXTINA (ketoconazole) FOAM |
| | KETODAN (ketoconazole) FOAM |

*Gel*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ciclopirox gel | NAFTIN (naftifine) GEL |

*Lotion*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | OXISTAT (oxiconazole) LOTION |

*Ointment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALEVAZOL (clotrimazole) OINTMENT | miconazole/zinc oxide/white petrolatum ointment |
| nystatin ointment | |
| nystatin – triamcinolone ointment | |
| VUSION (miconazole/zinc/white petrolatum) OINTMENT – *Brand Required* | |

*Powder*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KLAYESTA (nystatin) POWDER | |
| nystatin powder | |
| NYAMYC (nystatin) POWDER | |
| NYSTOP (nystatin) POWDER | |

*Shampoo*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ciclopirox shampoo | LOPROX (ciclopirox) SHAMPOO |
| ketoconazole shampoo | |

*Solution*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ciclopirox solution | CICLODAN (ciclopirox) SOLUTION |
| clotrimazole solution | EXELDERM (sulconazole) SOLUTION |
| | JUBLIA (efinaconazole) SOLUTION |
| | tavaborole solution |

*Suspension*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ciclopirox suspension | LOPROX (ciclopirox) SUSPENSION |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Onychomycosis Only:
  - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation.
  - The member must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.
- Other Diagnoses:
  - The member must have failed a trial of 3 preferred agents, for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.

# Eczema / Atopic Dermatitis

## Oral

### First Line Agents

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| azathioprine 50 mg | azathioprine 75 mg |
| cyclosporine | azathioprine 100 mg |
| methotrexate | |
| systemic oral corticosteroids | |

### *Prior Authorization Criteria*

- Azathioprine: See Preferred Dosage Form Criteria – Use enough 50 mg to make correct dosage

# Topical

## Aryl Hydrocarbon Receptor Agonist

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | VTAMA (tapinarof) 1% CREAM |

## Calcineurin Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tacrolimus 0.03% | ELIDEL (pimecrolimus) CREAM |
| tacrolimus 0.1% | pimecrolimus |

## Janus Kinase (JAK) inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| OPZELURA (ruxolitinib) 1.5% CREAM | |

## Phosphodiesterase 4 (PDE-4) inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EUCRISA (crisaborole) OINTMENT | ZORYVE (roflumilast) 0.15% CREAM |

## Topical Corticosteroids

Please see Topical Corticosteroids

# Systemic

*Interleukin (IL)-4/13 Inhibitor*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DUPIXENT (dupilumab) INJECTION | |

*Interleukin (IL)-13 Inhibitor*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ADBRY (tralokinumab-idrm) INJECTION | |
| EBGLYSS (lebrikizumab-lbkz) INJECTION | |

*Interleukin (IL)-31 Inhibitor*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | NEMLUVIO (nemolizumab) INJECTION |

*Janus Kinase (JAK) inhibitor*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CIBINQO (abrocitinib) TABLET | |
| OLUMIANT (baricitinib) TABLET | |
| RINVOQ ER (upadacitinib) TABLET | |

### *Electronic Age Verification*

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older.

### *Electronic Diagnosis Verification*

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

Prior Authorization Form – Atopic Dermatitis

*Initial Criteria – Approval Duration: 3 months*
- The member must have failed a 6-week trial of tacrolimus or pimecrolimus, as evidenced by paid claims or pharmacy printouts:
- One of the following must be met:
  - The member has failed a two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    OR
  - The member meets both of the following (1 AND 2):
    1. Affected area is on face, groin, axilla, or under occlusion.
    2. Member must have failed two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

*Vtama and Zoryve Only:*
- The member must have failed a 28-day trial with Eucrisa, as evidenced by paid claims or pharmacy printouts.

*Nemluvio Only:*
- The member must have failed a 3-month trial with Dupixent and an Interleukin (IL)-13 Inhibitor, as evidenced by paid claims or pharmacy printouts.

## Epidermolysis Bullosa

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| FILSUVEZ (birch triterpenes) |
| VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing* |

*Initial Criteria - Approval Duration: 12 months*
- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Genetic testing confirms pathogenic variant (e.g., KRT5 and KRT14).
- Baseline symptoms (e.g., extensive skin blistering, number and size of wounds) have been submitted.

*Renewal Criteria – Approval Duration: 12 months*
- The member has received a therapeutic response (e.g., extensive skin blistering, number and size of wounds) from baseline.

## Hidradenitis Suppurativa

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab – see Biosimilar Agents | |

### Interleukin (IL) – 17 Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

### Interleukin (IL)-17A and IL-17F inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | BIMZELX (bimekizumab-bkzx) |

#### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Cosentyx Only: The member must have failed a 90-day trial of adalimumab, as evidenced by paid claims or pharmacy printouts.
- Bimzelx Only: The member must have failed 90-day trials of adalimumab and Cosentyx as evidenced by paid claims or pharmacy printouts.

## Infantile Hemangioma

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| propranolol oral solution | HEMANGEOL (propranolol) ORAL SOLUTION |
| | timolol gel forming solution (used topically) |

#### *Electronic Age Verification*

- Hemangeol: The patient must be less than 1 years of age.

#### *Electronic Diagnosis Verification*

- Hemangeol: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- For timolol gel forming solution only:
  - One of the following must be met:
    - The member is being tapered off of treatment with propranolol oral solution
    - The member has a low risk and uncomplicated hemangioma (e.g., < 2 cm, not ulcerated and not located in central face, periorbital area, lips, chin, neck, oral cavity, lumbosacral, perineal, or perianal area)

- For Hemangeol Only:
  - The member must have failed a 3-month trial of the propranolol oral solution, as evidenced by paid claims or pharmacy printouts.

## Molluscum Contagiosum

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| ZELSUVMI (berdazimer) GEL |
| YCANTH (cantharidin) SOLUTION – *Medical Billing* |

*Initial Criteria - Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

## Lice / Scabies

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins) | CROTAN (crotamiton) |
| Ivermectin | malathion |
| NATROBA (spinosad) – *Brand Required Only* | SKLICE (ivermectin) |
| permethrin 5% cream | spinosad |
| LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID | |
| VANALICE (piperonyl butoxide/pyrethrins) GEL | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- One of the following must be met:
  - The member must have failed a 28-day/2-application trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
  - There is a documented community breakout of a strain that is not susceptible to the preferred agents.

## Plaque Psoriasis

### Biologics

**Interleukin (IL)-12/IL-23 Inhibitor**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SELARSDI (ustekinumab-aekn) |
| | STELARA (ustekinumab) |
| | STEQEYMA (ustekinumab-stba) |
| | ustekinumab-ttwe |
| | WEZLANA (ustekinumab-auub) |

| | |
|---|---|
| | YESINTEK (ustekinumab-kfce) |

**Interleukin (IL)-17A Inhibitor**

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TALTZ (ixekizumab) | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

**Interleukin (IL)-17A and IL-17F inhibitor**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | BIMZELX (bimekizumab-bkzx) |

**Interleukin (IL)-17 Receptor Inhibitor**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SILIQ (brodalumab) |

**Interleukin (IL)-23p19 Inhibitor**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ILUMYA (tildrakizumab-asmn) – *Medical Billing* |
| | SKYRIZI (risankizumab-rzaa) |
| | TREMFYA (guselkumab) |

**TNF Inhibitors**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab – see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| ENBREL (etanercept) | CIMZIA (certolizumab) VIAL – *Medical Billing* |
| infliximab - see Biosimilar Agents | |

*Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

*Electronic Step Therapy Required*

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab pegol has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of adalimumab, certolizumab pegol, or infliximab, as evidenced by paid claims or pharmacy printouts.

*Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Ilumya, Skyrizi and Tremfya Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Bimzelx, as evidenced by paid claims or pharmacy printouts.

- Ustekinumab Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, Bimzelx, Skyrizi or Tremfya, and Siliq, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Oral

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| acitretin 10 mg, 25 mg | acitretin 17.5 mg |
| cyclosporine | OTEZLA (apremilast) 20 MG |
| methotrexate | SOTYKTU (deucravacitinib) |
| OTEZLA (apremilast) 30 MG | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Acitretin 17.5 mg Only: See Preferred Dosage Form criteria
- Otezla 20 mg Only:
  - The member must weigh ≥ 20 kg and < 50 kg
  - The member must have failed a 3-month trial of adalimumab and an interleukin 17A inhibitor, as evidenced by paid claims or pharmacy printouts.
- Sotyktu Only: The member must have failed a trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - 30-day trial of Otezla
  - 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab)

## Topical

*Foams, Gel, Solution, Suspension*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcipotriene solution | calcipotriene/betamethasone suspension |
| calcipotriene foam | SORILUX (calcipotriene) FOAM |
| ENSTILAR (calcipotriene/betamethasone) FOAM | tazarotene gel |
| TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required* | |

*Cream, Lotion*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcipotriene cream | DUOBRII (halobetasol/tazarotene) LOTION |
| | tazarotene cream |
| | VTAMA (tapinarof) 1% CREAM |
| | ZORYVE (roflumilast) 0.3% CREAM |

*Ointment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcipotriene ointment | calcitriol ointment |
| calcipotriene/betamethasone ointment | |

### *Electronic Diagnosis Verification*

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
- Vtama Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
    - The member has had a 2-month trial of Zoryve, as evidenced by paid claims or pharmacy printouts.

## Prurigo Nodularis

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DUPIXENT (dupilumab) | NEMLUVIO (nemolizumab-ilto) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a dermatologist.
- The member is experiencing nodular lesions that produce itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member has failed a 2-week trial of a topical corticosteroid of at least high potency, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agent Criteria*

- The member must have failed a 3-month trial of Dupixent, as evidenced by paid claims or pharmacy printouts.

## Seborrheic Dermatitis

See Antifungals – Topical
See Steroids – Topical

### *Topical Phosphodiesterase-4 (PDE-4) Inhibitors*

| CLINICAL PA REQUIRED |
|---|
| ZORYVE (roflumilast) FOAM |

### *Electronic Diagnosis Verification*

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must have had a 4-week trial of concurrent use of a topical antifungal (shampoo or foam) AND a high potency topical corticosteroid (foam, spray or shampoo) , as evidenced by paid claims or pharmacy printouts..

## Steroids – Topical

### Super-High Potency (Group 1)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | clobetasol emollient | 0.05% | | |
| | clobetasol propionate | 0.05% | | |
| | fluocinonide | 0.10% | | |
| | halobetasol propionate | 0.05% | | |
| Lotion | betamethasone dipropionate, augmented | 0.05% | IMPEKLO (clobetasol) | 0.05% |
| | clobetasol propionate | 0.05% | ULTRAVATE (halobetasol) MDP | 0.05% |
| Ointment | betamethasone dipropionate, augmented | 0.05% | | |
| | clobetasol propionate | 0.05% | | |
| | clobetasol propionate foam | 0.05% | | |
| | halobetasol propionate | 0.05% | | |
| Foam, Gel, Shampoo, Solution, Spray | clobetasol propionate shampoo | 0.05% | betamethasone dipropionate, augmented gel | 0.05% |
| | clobetasol propionate solution | 0.05% | clobetasol emulsion foam | 0.05% |
| | clobetasol propionate spray | 0.05% | STEP 2*halobetasol propionate foam | 0.05% |
| | clobetasol propionate gel | 0.05% | | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Electronic Duration Verification*

Group 1 topical steroids are covered for 30 days every 90 days. Group 1 steroids are covered with group 2 steroids to facilitate an alternating schedule.

- If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604: *Approval: 1 year*
    - Location of application: palms, soles, or psoriatic crusts
    - Indication: psoriasis
    - Close monitoring for side effects

**Reference:**
Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Group 1 topical steroids to no more than twice daily up to 4 weeks. Transitions to lower potent agents, intermittent therapy, and combination treatment with non-steroids are recommended to minimize side effects.

## High Potency (Group 2)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | betamethasone dipropionate, augmented | 0.05% | APEXICON E (diflorasone emollient) | 0.05% |
| | desoximetasone | 0.25% | | |
| | fluocinonide | 0.05% | | |
| | HALOG (halcinonide)– *Brand Required* | 0.10% | | |
| Lotion | | | BRYHALI (halobetasol) LOTION | 0.01% |
| Ointment | betamethasone dipropionate | 0.05% | diflorasone diacetate | 0.05% |
| | desoximetasone | 0.25% | | |
| | fluocinonide | 0.05% | | |
| | fluticasone propionate | 0.01% | | |
| | HALOG (halcinonide) | 0.10% | | |
| Gel, Solution, Spray | desoximetasone spray | 0.25% | desoximetasone gel | 0.05% |
| | fluocinonide gel | 0.05% | halcinonide solution | 0.10% |
| | fluocinonide solution | 0.05% | HALOG (halcinonide) SOLUTION | 0.10% |

## High Potency (Group 3)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | betamethasone dipropionate | 0.05% | STEP2*amcinonide | 0.10% |
| | triamcinolone acetonide | 0.50% | desoximetasone | 0.05% |
| | | | STEP2*diflorasone diacetate | 0.05% |
| | | | fluocinonide-E | 0.05% |
| Lotion | | | amcinonide | 0.10% |
| Ointment | betamethasone valerate | 0.10% | desoximetasone | 0.05% |
| | fluticasone propionate | 0.01% | | |
| | mometasone furoate | 0.10% | | |
| | triamcinolone acetonide | 0.50% | | |
| Foam | betamethasone valerate foam | 0.12% | | |

## Medium Potency (Group 4)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | clocortolone pivalate | 0.10% | PANDEL (hydrocortisone probutate) | 0.1% |
| | fluticasone propionate | 0.05% | | |
| | mometasone furoate | 0.10% | | |
| | triamcinolone acetonide | 0.10% | | |
| Ointment | fluocinolone acetonide | 0.025% | hydrocortisone valerate | 0.20% |
| | triamcinolone acetonide | 0.10% | STEP2*flurandrenolide | 0.05% |

| | | | | |
|---|---|---|---|---|
| | triamcinolone acetonide | 0.05% | | |
| Aerosol, Paste Solution | mometasone furoate solution | 0.10% | triamcinolone acetonide aerosol | 0.147 MG/G |
| | triamcinolone acetonide paste | 0.10% | | |

## Lower-Mid Potency (Group 5)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | betamethasone valerate | 0.10% | fluocinolone acetonide | 0.025% |
| | hydrocortisone valerate | 0.20% | prednicarbate | 0.10% |
| | | | STEP2*flurandrenolide | 0.05% |
| | | | hydrocortisone butyrate | 0.10% |
| | | | hydrocortisone butyrate emollient | 0.10% |
| Lotion | betamethasone dipropionate | 0.05% | STEP2*flurandrenolide | 0.05% |
| | LOCOID (hydrocortisone butyrate) – *Brand Required* | 0.10% | fluticasone propionate | 0.05% |
| | triamcinolone acetonide | 0.10% | | |
| Ointment | desonide | 0.05% | hydrocortisone butyrate | 0.10% |
| | triamcinolone acetonide | 0.025% | prednicarbate | 0.10% |
| Gel, Solution | hydrocortisone butyrate solution | 0.10% | desonide gel | 0.05% |

## Low Potency (Group 6)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | alclometasone dipropionate | 0.05% | fluocinolone acetonide | 0.01% |
| | desonide | 0.05% | | |
| | triamcinolone acetonide | 0.03% | | |
| Lotion | betamethasone valerate lotion | 0.10% | | |
| | desonide lotion | 0.05% | | |
| | triamcinolone acetonide lotion | 0.025% | | |
| Ointment | alclometasone dipropionate | 0.05% | | |
| Oil, Solution | fluocinolone acetonide oil | 0.01% | | |
| | fluocinolone acetonide solution | 0.01% | | |

## Least Potent (Group 7)

| Dosage Form | PREFERRED AGENTS (NO PA REQUIRED) | | NON-PREFERRED AGENTS (PA REQUIRED) | |
|---|---|---|---|---|
| Cream | hydrocortisone | 1.00% | | |
| | hydrocortisone | 2.50% | | |
| Lotion | hydrocortisone | 2.50% | | |
| Ointment | hydrocortisone | 1.00% | | |
| | hydrocortisone | 2.50% | | |

| | | | | |
|---|---|---|---|---|
| Solution | | | hydrocortisone solution | 2.50% |
| | | | TEXACORT (hydrocortisone) SOLUTION | 2.50% |

*Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

*Agents labeled as "STEP 2"*

- The member must have failed a 2-week trial of all preferred and non-preferred drug entities not labeled "STEP 2" within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

# Endocrinology

## Androgens

### Injectable

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| testosterone cypionate injection | AVEED (testosterone undecanoate) |
| testosterone enanthate injection | AVEED (testosterone undecanoate) – *Medical Billing* |
| | AZMIRO (testosterone cypionate) syringe – *Medical Billing* |
| | DEPO-TESTOSTERONE (testosterone cypionate) |
| | XYOSTED (testosterone enanthate) |

### Oral

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| JATENZO (testosterone undecanoate) | methyltestosterone |
| TLANDO (testosterone undecanoate) | METHITEST (methyltestosterone) |

### Topical

*Gel Packet*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| testosterone 1% (50mg/5g) gel packet | ANDROGEL (testosterone) GEL PACKET |
| testosterone 1% (25mg/2.5g) gel packet | testosterone 1.62% (20.25mg/1.25g) gel packet |
| | testosterone 1.62% (40.5mg/2.5g) gel packet |
| | VOGELXO (testosterone) GEL PACKET |

*Gel Pump*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ANDROGEL (testosterone) GEL MD PUMP – *Brand Co-Preferred* | VOGELXO (testosterone) GEL PMP |
| testosterone 2% (10mg/0.5g) gel MD PMP bottle | |

| | |
|---|---|
| testosterone 1% (12.5mg/1.25g) gel MD PMP bottle | |
| testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle | |
| testosterone 2% (30mg/1.5g) solution MD PMP | |

*Gel Tube*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TESTIM (testosterone) GEL TUBE – *Brand Co-Preferred* | VOGELXO (testosterone) GEL TUBE |
| testosterone 1% (50mg/5g) gel tube | |

*Nasal Gel*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | NATESTO (testosterone) GEL MD PMP |

*Patch*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ANDRODERM (testosterone) PATCH | |

*Solution MDP*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| testosterone (30mg/1.5mL) | |

*Pellet*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TESTOPEL (testosterone) PELLET – *Medical Billing* | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

# Cushing Syndrome

## Adrenal Enzyme Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ketoconazole | ISTURISA (osilodrostat) |
| LYSODREN (mitotane) | RECORLEV (levoketoconazole) |
| METOPIRONE (metyrapone) | |

### *Electronic Diagnosis Verification*

- Isturisa and Recorlev: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization*

*Initial Criteria – Approval Duration: 6 months*
- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy printouts..
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

*Renewal Criteria – Approval Duration: 12 months*
- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

## Glucocorticoid Receptor Antagonist

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| mifepristone 200 mg | KORLYM (mifepristone) – *Brand Required* |
| | mifepristone 300 mg |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization*

*Initial Criteria – Approval Duration: 6 months*
- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy print outs.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7% or TIR < 70%, despite adherence to an anti-diabetes regimen.
- See Preferred Dosage Form Criteria

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced and maintained an improvement in cushingoid appearance, acne, hirsutism, striae, psychiatric symptoms, or excess total body weight.
- The member has improved hyperglycemia as a hemoglobin A1c decrease of 1% or greater or increase in TIR of 10% not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

**References:**


- Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." *The lancet Diabetes & endocrinology* 9.12 (2021): 847-875.

# Diabetes

**References:**

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

**Covered options in combination with Insulin therapy:**

- GLP-1 agonists, DPP-4 inhibitors, SGLT-2 inhibitors, TZDs, and metformin
  - GLP-1 Agonist and SGLT-2 inhibitors are recommended first line treatments for every pathway indicated in the guidelines (ASCVD, HF, CKD, hypoglycemia risk, and to minimize weight gain)
  - TZDs increase insulin sensitivity and hypoglycemia risk should be monitored.
  - Metformin is recommended throughout treatment escalation.

### *Therapeutic Duplication*

- One Strength of one medication is allowed at a time.
- Medication classes not payable together:
  - DPP-4 Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP-4 Inhibitors should not be used concurrently due to similar mechanisms of action.
  - Sulfonylureas and Insulins
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued.
  - Humulin R U-500 is not allowed with any other insulin (basal or prandial)
    - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

### *Underutilization*

- Toujeo, Tresiba, and Metformin 1000 mg must be used adherently and will reject on point of sale for late fill.

## Biologics

| **CLINICAL PA REQUIRED** |
|---|
| TZIELD (teplizumab-mzwv) – *Medical Billing* |

**High-Cost Drug:**

This 14-day treatment course costs $193,900.

- In study TN-10; 72 people were enrolled – 44 in active treatment group and 32 in placebo group. By month 36, 63.7% (28) in the active treatment group and 71.9% (23) in the placebo group had experienced Stage 3 Type 1 Diabetes onset.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an endocrinologist.
- The member has a family history of Type 1 Diabetes
- The member has at least two of the following pancreatic islet cell autoantibodies:
  - Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - Insulin autoantibody (IAA)

    - Insulinoma-associated antigen 2 autoantibody (IA-2A)
    - Zinc transporter 8 autoantibody (ZnT8A)
    - Islet cell autoantibody (ICA)
- The member has no symptoms of Type 1 Diabetes (e.g., polyuria, polydipsia, weight loss, fatigue, DKA)
- The member has abnormal blood sugar levels determined by an oral glucose tolerance test.

## DPP-4 Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| JANUMET (sitagliptin/metformin) | alogliptan/pioglitazone |
| JANUMET XR (sitagliptin/metformin) | alogliptin |
| JANUVIA (sitagliptin) | alogliptin/metformin |
| JENTADUETO (linagliptin/metformin) | KAZANO (alogliptin/metformin) |
| JENTADUETO XR (linagliptin/metformin) | NESINA (alogliptin) |
| TRADJENTA (linagliptin) | ONGLYZA (saxagliptin) |
| | OSENI (alogliptin/pioglitazone) |
| | saxagliptin |
| | saxagliptin/metformin |
| | sitagliptin/metformin |
| | ZITUVIMET XR (sitagliptin/metformin) |
| | ZITUVIO (sitagliptin) |

++Clinically Non-Preferred: Alogliptin and saxagliptan have a potentially higher risk for heart failure.

### *Electronic Age Verification*

- The member must be 18 years or older for Januvia, Janumet, or Janumet XR

### *Electronic Concurrent Medications Required*

- A total of 28-day supply of metformin must be paid within 100 days prior to the DPP-4 Inhibitor's date of service. Members with GI intolerances to high dose IR metformin must trial at minimum a dose of 500 mg ER, as evidenced by paid claims or pharmacy printouts..
    - Metformin is recommended to be continued with therapy with DPP-4 Inhibitors**.** If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C or TIR and are first line alternatives.

* GI intolerances (typically will not be considered to bypass trial requirements):
- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER, as evidenced by paid claims or pharmacy printouts.
- Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

**References:**

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy, as evidenced by paid claims or pharmacy printouts.
- Zituvio and sitagliptin/metformin only: See Preferred Dosage Form Criteria

## DPP-4 Inhibitors / SGLT2 Inhibitors Combination

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TRIJARDY XR (empagliflozin/linagliptan/metformin) | GLYXAMBI (empagliflozin/linagliptin) |
| | STEGLUJAN (ertugliflozin/sitagliptin) |
| | ++QTERN (dapagliflozin/saxagliptin) |

++Clinically Non-Preferred: Saxagliptan has a potentially higher risk for heart failure.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form Criteria
- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

## GLP-1 Agonists^

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED) | NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED) |
|---|---|---|
| VICTOZA (liraglutide)<br>- *Brand Required* | BYDUREON BCISE (exenatide microspheres) | ++BYETTA (exenatide) |
| | OZEMPIC (semaglutide) | liraglutide |
| | RYBELSUS (semaglutide) | TRULICITY (dulaglutide) |

++Clinically Non-Preferred: Byetta is less effective than other available agents.
^ See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

Clinical information: dose comparison recommendations for switching between GLP-1 agonists

- For GI side effects (start titration at lowest available dose)
- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
    - Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg = Rybelsus 7 mg
    - Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 14 mg = Mounjaro 2.5 mg
    - Trulicity 3 mg = Ozempic 0.5 mg or 1 mg
    - Trulicity 4.5 mg = Ozempic 1 mg
    - Mounjaro 5 mg = Ozempic 2 mg

**References:**

1. Almandoz JP, Lingvay I, Morales J, Campos C. Switching Between Glucagon-Like Peptide-1 Receptor Agonists: Rationale and Practical Guidance. Clin Diabetes. 2020 Oct;38(4):390-402. Doi: 10.2337/cd19-0100. PMID: 33132510; PMCID: PMC7566932.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Step 1: Ozempic, Rybelsus, Bydureon Bcise:
    - One of the following apply (A or B):
        A. The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite a 90-day trial of triple combination therapy with Victoza, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.

- If triple therapy cannot be met with Victoza, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent (metformin must be used as tolerated).
- If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza + two other agents (metformin, SGLT-2 inhibitor or insulin must be used as tolerated).

B. The request is for Ozempic, as evidenced by paid claims or pharmacy printouts, and is eligible for approval for semaglutide based on the MASH criteria or tirzepatide based on the Sleep Apnea criteria.

- Step 2:

A. The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
   1. If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.
   2. If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).

B. One of the following have been met:
   1. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
   2. The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects; GI effects are common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

## GIP/GLP-1 Agonists

| CLINICAL PA REQUIRED |
|---|
| MOUNJARO (tirzepatide) |

### *Prior Authorization Criteria*

*<u>Initial Criteria – Approval Duration:</u> 12 months*

- One of the following is met (A or B):

A. The member meets both of the following (1 and 2):
   1. The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
      - If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.

- If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).

2. One of the following have been met (a or b):
   a. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
   b. The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

B. The request is for Mounjaro and the member is otherwise eligible for approval for tirzepatide based on the Sleep Apnea criteria.

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

Note: If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized.

## Gastroparesis

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| metoclopramide tablet | GIMOTI (metoclopramide nasal spray) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- Clinical justification must be provided explaining why the member is unable to use an oral dosage formulation (including solution formulations), subject to clinical review.

## Glucose Rescue Medications

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BAQSIMI (glucagon) SPRAY – Labeler 00548 | BAQSIMI (glucagon) SPRAY – Labeler 00002 |
| glucagon kit – labeler 00002 | glucagon kit – labeler 63323, 00548 |
| GVOKE (glucagon) INJECTION | |
| ZEGALOGUE (dasiglucagon) AUTOINJECTOR | |

### *Electronic Duration Verification*

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for a hypoglycemic episode. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

## Insulin/GLP-1 Agonist Combination

| CLINICAL PA REQUIRED |
|---|
| SOLIQUA (insulin glargine/lixisenatide) |
| XULTOPHY (insulin degludec/liraglutide) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

## Insulin

### Rapid Acting Insulin

**Insulin Lispro**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HUMALOG U-100 (insulin lispro) CARTRIDGE | insulin lispro vials – See Biosimilar Agents |
| insulin lispro U-100 pen, jr pen | |

**Insulin Aspart**

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FIASP (insulin aspart) | insulin aspart |
| | NOVOLOG (insulin aspart) |
| | RELION NOVOLOG (insulin aspart) |

**Insulin Glulisine**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | APIDRA (insulin glulisine) |

**Insulin Regular, Human**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ++AFREZZA (insulin regular, human) |
| | ++HUMULIN R (insulin regular, human) VIAL |
| | ++NOVOLIN R (insulin regular, human) |
| | ++ RELION NOVOLIN R (insulin regular, human) |

++Clinically Non-Preferred: ACOG (American College of Obstetricians and Gynecologists) guidelines prefer insulin analogues (insulin aspart and lispro) over regular insulin due to better compliance, better glycemic control, and overall fewer hypoglycemic episodes.

### *Electronic Step Therapy Required*

- Fiasp
  - PA Not Required Criteria: A 3-month supply of insulin lispro has been paid within 180 days prior to Fiasp's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial from insulin lispro, as evidenced by paid claims or pharmacy printouts.
- Insulin Vials

- PA Not Required Criteria: A 28-day supply of Omnipod has been paid within 90 days prior to insulin lispro vial's date of service.
- PA Required Criteria: The member has an insulin pump.

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Apidra: The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - insulin lispro
  - Fiasp
- Humalog U-200: Request must not be for use in an insulin pump: HUMALOG® (insulin lispro) 200 Units/mL: Do Not Use in a Pump (lillymedical.com)
  - Doses ≤ 200 units/day: Clinical justification must be provided why member cannot tolerate the volume of insulin required to use Humalog U-100 or tolerate two injections per dose.
  - Doses > 200 units/day: Clinical justification must be provided why member is not a candidate for Humulin R U-500.
- Regular Insulin (Humulin R / Novolin R / Afrezza): The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - insulin lispro
  - Fiasp
- Non-Preferred Agents: See Preferred Dosage Form Criteria

## Intermediate Acting Insulin

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| HUMULIN R U-500 (insulin regular, human) | ++ NOVOLIN N (insulin NPH human isophane) | ++ HUMULIN N (insulin NPH human isophane) |
| | ++ RELION NOVOLIN N (insulin NPH human isophane) | |

++ Clinically non-preferred: Lantus have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)*

- One of the following must be met:
  - The member must be pregnant or breastfeeding.
  - The member must be tube feedings.
  - The member must be post-solid organ transplant.
    - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
  - Clinical justification explaining why the member is unable to use Lantus (subject to clinical review)

*Non-Preferred Agent Criteria*

- See Preferred Dosage Form Criteria

## Long-Acting Insulin

### Insulin Glargine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| LANTUS U-100 (insulin glargine)<br>*– Brand Required* | insulin glargine U-100 (generic Toujeo) |
| TOUJEO U-300 (insulin glargine)<br>*No PA required for doses 100 unit/day to 200 unit/day<br>*– Brand Required* | insulin glargine (Lantus) – See Biosimilar Agents |

### Insulin Degludec

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TRESIBA (insulin degludec) FLEXTOUCH U-200<br>*No PA required for doses 100 unit/day to 200 unit/day<br>*- Brand Required* | insulin degludec U-100 and U-200 |
| | TRESIBA (insulin degludec) U-100 |

#### *Quantity Override Request*

- Toujeo Solostar 300 unit/mL, Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  - A. Doses > 200 units/day:
    - Clinical justification must be provided explaining why the member is not a candidate for U-500R + Toujeo and Tresiba are not intended as replacements for U-500R insulin
  - B. Doses >100 units/day to ≤ 200 units/day: No prior authorization required.
    - Please call for an override by calling provider relations at 1-800-755-2604 if the day supply is less than 30 days and dose is between 100 units/day and 200 units/day (e.g., short-cycle filling).
  - C. Doses ≤ 100 units/day:
    - Must meet Prior Authorization Criteria below

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
- The member has had a 90-day trial of Lantus with good compliance, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met, as evidenced by provided clinical notes or labs:
  - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
  - The member must be experiencing inconsistent blood sugars.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced at least one of the following, as evidenced by provided clinical notes or labs:
  - Reduction in frequency and/or severity of hypoglycemia
  - Improved glycemic control (evidenced by A1c or TIR)

## Mixed Insulin

### Insulin NPL/Insulin Lispro

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL | HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN |
| insulin lispro mix 75/25 kwikpen | HUMALOG MIX 75/25 (insulin NPL/insulin lispro) |

### Insulin Aspart Protamine/Insulin Aspart

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| insulin aspart protamine/insulin aspart 70/30 | NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) – *Brand Required* |
| | RELION NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) |

### Insulin NPH Human/Regular Insulin Human

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HUMULIN MIX 70/30 (insulin NPH human/regular insulin human) | NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human) |
| | RELION NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)*

- Humulin 70/30 and Novolin 70/30 only:
  - One of the following must be met:
    - Member must be pregnant or breastfeeding.
    - Member must be on tube feedings.
    - Member must be post-solid organ transplant.
      - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

*Non-Preferred Agent Criteria*

- See Preferred Dosage Form Criteria
- Clinical justification must be provided explaining why the member is unable to use the preferred products or a long acting plus short acting regimen (subject to clinical review).

## SGLT2 Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FARXIGA (dapagliflozin) – *Brand Required* | dapagliflozin |
| JARDIANCE (empagliflozin) | dapagliflozin/metformin XR 5mg-1000mg, 10mg-1000mg |
| SYNJARDY (empagliflozin/metformin) | INVOKANA (canagliflozin) |
| XIGDUO XR (dapagliflozin/metformin) 5 MG-500 MG, 5 MG-1000 MG, 10 MG-500 MG, 10 MG-1000 MG – *Brand Required* | INVOKAMET (canagliflozin/metformin) |
| | INVOKAMET XR (canagliflozin/metformin) |
| | STEGLATRO (ertugliflozin) |
| | SEGLUROMET (ertugliflozin/metformin) |
| | SYNJARDY XR (empagliflozin/metformin) |
| | XIGDUO XR (dapagliflozin/metformin) 2.5 MG – 1000 MG |

++ Canagliflozin has shown an increase in the risk of lower limb amputations and fractures in studies.
++ Dapagliflozin did not reduce atherosclerotic cardiovascular morbidity or mortality in a primary analysis, however it decreased cardiovascular in the sub analysis of prior myocardial infarction.
++ Ertugliflozin was not superior to placebo in reducing the primary composite cardiovascular endpoint.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents and other classes of medication (subject to clinical review).

**References:**

1. DeSantis A. Sodium-glucose cotransporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

## Sulfonylureas

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| glimepiride 1 mg, 2 mg, and 4 mg | glimepiride 3 mg |
| glipizide IR 5 mg, 10 mg | glipizide 2.5 mg |
| glipizide ER | ++glyburide |
| glipizide/metformin | ++glyburide/metformin |
| glipizide ER | ++glyburide, micronized |

++Clinically Non-preferred: Glyburide is not recommended due to hypoglycemia.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of glipizide and glimepiride, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

## Growth Hormone

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| GENOTROPIN (somatropin) | HUMATROPE (somatropin) |
| GENOTROPIN MINIQUICK (somatropin) | NGENLA (somatrogon-ghla) |
| NORDITROPIN FLEXPRO (somatropin) | NUTROPIN AQ NUSPIN (somatropin) |
| **PREFERRED AGENTS (PA REQUIRED)** | OMNITROPE (somatropin) |
| SKYTROFA (lonapegsomatropin-tcgd) | SAIZEN (somatropin) |
| | SOGROYA (somapacitan-beco) |
| | ZOMACTON (somatropin) |

### *Prior Authorization Criteria*

Prior Authorization Form – Growth Hormone

*Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)*

- Member must have one of the following covered diagnoses (listed below):
  - Panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome
  - SHOX syndrome

- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- Endogenous growth hormone deficiency

- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
- Skytrofa and Omnitrope Only: The member must have failed a 30-day trial of Norditropin or Genotropin, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form Criteria

*Chronic Renal Insufficiency*

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

*Endogenous Growth Hormone Deficiency, panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)*

- ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
  - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.
  - For infants less than 18 months old, both of the following criteria are met:
    - The member has a plasma glucose level less than 70 mg/dL
    - The member has GH level < 5 mcg/L

*Prader-Willi Syndrome (PWS)*

See covered medications for weight loss

- The member must not have severe obesity (class 2) defined as ≥ 120% of the 95$^{th}$ percentile for age and gender
- If the member has obesity ≥ 95$^{th}$ percentile and < 120% of the 95$^{th}$ percentile for age and gender, all the following must be met (*6-month approval criteria*):
  - The prescriber must attest that member will meet with a dietician every 3 months
  - The member must have had a sleep study to rule out sleep apnea
  - The member must not have non-alcoholic fatty liver disease
  - The member must not have an A1c > 5.7%

*Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met )*

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

*Prader-Willi Syndrome*

- If the member has obesity ≥ 95$^{th}$ percentile and < 120% of the 95$^{th}$ percentile for age and gender, initial criteria must be met in addition to the following *(6-month approval criteria)*:

- The member must have met with a dietician at least 2 times in the past 6 months

**References:**


1. Deal et al,. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader Will syndrome. J Clin Endocrin Metab. 2013. doi: 10.1210/jc.2012-3888


## Serostim

| CLINICAL PA REQUIRED |
| --- |
| SEROSTIM (somatropin) |

### *Prior Authorization Criteria*

Prior Authorization Form – Growth Hormone

*Initial Criteria – Approval Duration: 3 months*

- The member must not have an active malignancy.
- The requested medication must be prescribed by, or in consult with, and infectious disease specialist or a specialist in the diagnosis and management of HIV infection.
- The member must be on concomitant antiretroviral therapy.
- The member must have failed a 3-month trial with megestrol, as evidenced by paid claims or pharmacy printouts.
- Lean body mass and body weight must be provided.
- Baseline physical endurance must be provided.

*Renewal Criteria – Approval Duration: 8 months (one time)*

- Lean body mass and body weight must have increased from baseline.
- Physical endurance must have increased from baseline.

## Imcivree

| CLINICAL PA REQUIRED |
| --- |
| IMCIVREE (setmelanotide) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 4 months*

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95$^{th}$ percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC)
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:

- Rod-cone dystrophy
- Polydactyly
- Genital anomalies
- Renal anomalies
- Intellectual impairment

*Renewal Criteria – Approval Duration: 12 months*

- One of the following must be met since starting treatment with Imcivree:
  - Members ≥ 18 years old:
    - First renewal – a 5% weight reduction has been achieved or maintained.
    - Subsequent renewal – a 10% weight reduction has been achieved or maintained.
  - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained.

## Hypothyroidism

*Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| levothyroxine tablet | EUTHYROX (levothyroxine) TABLET |
| | levothyroxine capsule |
| | LEVO-T (levothyroxine) TABLET |
| | LEVOXYL (levothyroxine) TABLET |
| | SYNTHROID (levothyroxine) TABLET |
| | UNITHROID (levothyroxine) TABLET |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration:* 12 months

- Levothyroxine capsule only: The member must have documented celiac disease, yellow dye allergy, or lactose/milk protein allergy.
- All other agents: See Preferred Dosage Form criteria

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ERMEZA (levothyroxine) SOLUTION | THYQUIDITY (levothyroxine) ORAL SOLUTION |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration:* 12 months

- All other agents: See Preferred Dosage Form criteria

## Secondary Hyperparathyroidism

*Oral*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcitriol | cinacalcet |
| paricalcitol | doxercalciferol capsule |

| | |
|---|---|
| | HECTOROL (doxercalciferol) CAPSULE |
| | RAYALDEE ER (calcifediol) |
| | ROCALTROL (calcitriol) |
| | SENSIPAR (cinacalcet) |
| | ZEMPLAR (paricalcitol) |

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Cinacalcet only:*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

*All other agents:*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

**References:**

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

### *Intravenous*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | PARSABIV (etelcalcetide) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must be on renal dialysis, so Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
- The requested medication must be prescribed by, or in consult with, an endocrinologist or nephrologist
- The member has been unable to maintain iPTH (intact parathyroid hormone) between 2-7 times ULN with previous trials of a vitamin D analog AND cinacalcet as evidenced by paid claims or pharmacy printouts

*Renewal Criteria – Approval Duration: 12 months*

- The member has documented one of the following:
  - At least 30% reduction from baseline in mean iPTH
  - Decreased levels of corrected total serum calcium from baseline, while levels remain ≥ 8.4 mg/dL

### *Subcutaneous*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | YORVIPATH (palopegteriparatide) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent, as evidenced by paid claims or pharmacy printouts.:
    - Symptomatic hypocalcemia
    - Hyperphosphatemia
    - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be ≥ 7.8 mg/dL
- The member must have a magnesium concentration ≥ 1.3 mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

*Renewal Criteria – Approval Duration: 12 months*

- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath
- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

## Precocious Puberty

| NO PA REQUIRED | |
|---|---|
| FENSOLVI (leuprolide) – *Medical Billing* | SUPPRELIN LA (histrelin) – *Medical Billing* |
| LUPRON PED DEPOT (leuprolide) – *Medical Billing* | |
| SYNAREL (nafarelin) – *Medical Billing* | |
| TRIPTODUR (triptorelin) – *Medical Billing* | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 1 month*

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Thyroid Eye Disease

| CLINICAL PA REQUIRED |
|---|
| TEPEZZA (teprotumumab-trbw) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months (8 infusions per lifetime)*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist, ophthalmologist, or specialist in the treatment of Thyroid Eye Disease (TED)
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member has one of the following:
    - Inflamed eyes with increasing diplopia

- Proptosis ≥ 3 mm above ULN
- Lid retraction of > 2 mm
- Moderate to severe-soft tissue involvement

- The provider must submit each of the following:
  - Free thyroxine (FT4) and free triiodothyronine (FT3) levels are within normal limits
  - Must have a Clinical Activity Score ≥4
- The member has failed a one-month trial of a maximally tolerated indicated dose of IV systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.

## Tumor-Induced Osteomalacia

| CLINICAL PA REQUIRED |
|---|
| CRYSVITA (burosumab) – *Medical Billing* |

*Initial Criteria – Approval Duration: 12 months*

- The diagnosis has been confirmed by a serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL with unresectable phosphaturic mesenchymal tumor

*Renewal Criteria – Approval Duration: 12 months*

- The member has received a therapeutic response as evidenced by normalization of serum phosphate levels, improved ambulation, healing of bone fractures, or reduced pain.

## X-linked Hypophosphatemia (XLH)

| CLINICAL PA REQUIRED |
|---|
| CRYSVITA (burosumab) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- The diagnosis has been confirmed by one of the following:
  - Family history of XLH, low serum phosphate, and increased alkaline phosphatase (ALP)
  - Genetic testing confirming a pathogenic mutation of the phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX gene)
  - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
- If the member is 18 years or older, one of the following must be met:
  - The member's epiphyseal plate has not fused
  - The member has bone fractures
  - The member has had a 3-month trial of conventional treatment with oral phosphate supplementation combined with active vitamin D (e.g., calcitriol), as evidenced by paid claims or pharmacy printouts, and continues to have significant musculoskeletal pain and limited mobility

*Renewal Criteria – Approval Duration: 12 months*

- For members 18 years and older: the member has received a therapeutic response as evidenced by improvement in bone pain, mobility, or healing of bone fractures) in addition to one of the following:
  - Normalization of phosphate levels
  - Normalization of bone-specific alkaline phosphatase activity
  - Normalization of tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- For members younger than 18 years old: One of the following must be met:
  - Increased serum phosphate levels

- Increased tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- Decreased of serum alkaline phosphatase activity

## Weight Loss

### *Antipsychotic Induced Weight Gain*

- Metformin is covered without prior authorization.
- Victoza is covered without prior authorization by submitting diagnosis code T43.505A
  - For doses greater than 1.8 mg/day, please call for an override by calling provider relations at 1-800-755-2604:

### *Obesity*

- The following drugs are covered without prior authorization by submitting a corresponding diagnosis code for the indication:
  - phentermine, bupropion, naltrexone, topiramate

# GI – Gastroenterology

## Acid Blockers

### Proton Pump Inhibitor

### Solid Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| lansoprazole | esomeprazole magnesium | ACIPHEX (rabeprazole) |
| omeprazole | | DEXILANT (dexlansoprazole) |
| pantoprazole | | dexlansoprazole |
| rabeprazole | | NEXIUM (esomeprazole) |
| | | omeprazole-sodium bicarbonate |
| | | PREVACID (lansoprazole) |
| | | PRILOSEC (omeprazole) |
| | | PROTONIX (pantoprazole) |
| | | ZEGERID (omeprazole/sodium bicarbonate) |

### *Electronic Step Therapy Required*

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 14-day supply from at least 1 preferred agent at max dose has been paid within 365 days prior to preferred step 1 agent's date of service.
  - PA Required Criteria: The member must have failed a 14-day trial from at least 1 preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- Non-Preferred Agents Criteria – Step 2 Agents:
  - Member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

## Non-Solid Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED (PA REQUIRED) |
|---|---|
| lansoprazole ODT | esomeprazole solution packet |
| NEXIUM (esomeprazole) PACKET- *Brand Required* | KONVOMEP (omeprazole/sodium bicarbonate) |
| PROTONIX (pantoprazole) PACKET *– Brand Required* | omeprazole-sodium bicarbonate packet |
| | pantoprazole packet |
| | PREVACID (lansoprazole) SOLUTAB |
| | PRILOSEC SUSPENSION (omeprazole) |
| | ZEGERID (omeprazole-sodium bicarbonate) PACKET |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- Member must have failed a 30-day trial with all preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

### *Electronic Age Verification*

- Nexium 2.5 mg and 5 mg Packet: The member must be less than 1 years old (or less than 7.5 kg)

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:
    - Member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
    - H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

**References**

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-28.

2. Fackler WK, Ours TM, Vaezi MF, Richter JE. Long-term effect of H2RA therapy on nocturnal gastric breakthrough. Gastroenterology. 2002;122:625-632.

## Potassium Competitive Acid Blocker

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| VOQUEZNA (vonoprazan) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet one of the following criteria (A, B, or C):
  - The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Omeprazole twice daily
    - Rabeprazole or esomeprazole daily.
  - The member has severe esophagitis (LA Grade C/D disease)
  - Member must have failed a 30-day trial with all preferred proton pump inhibitors (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

## Acute Hepatic Porphyria (AHP)

| CLINICAL PA REQUIRED |
|---|
| GIVLAARI (givosiran) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, hepatologist, hematologist, gastroenterologist, or specialist in acute hepatic porphyria (AHP)
- The member must have a diagnosis of AHP (e.g., acute intermittent porphyria (AIP), porphyria cutanea tarda (PCT), erythropoietic protoporphyria (EPP)) with one of the following as defined by laboratory reference range:
  - Elevated urine porphobilinogen (PBG)
  - Genetic testing confirming a pathogenic mutation (e.g., *HMBS/PBGD*)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration
- The member has not had a liver transplant.
- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, stress)If the member is a current tobacco/marijuana user, the member must have received tobacco/marijuana cessation counseling in the past year
- If the member has a history of alcohol use within the past 5 years, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

*Renewal Criteria – Approval Duration: 12 months*

- The member has had a meaningful reduction (e.g., 30%) in each of the following:

- Number of porphyria attacks
- Days of Hemin use
- Reduction in *ALAS1 levels* and urinary ALA and PBG

## Bowel Prep Agents

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| GAVILYTE-C | CLENPIQ |
| GAVILYTE-G | PEG 3350/SOD SUL/NACL/KCL/ASB/C |
| GAVILYTE-N | PLENVU |
| GOLYTELY 236-22.74G – *Brand Co-Preferred* | |
| MOVIPREP – *Brand Required* | |
| PEG-3350 AND ELECTROLYTES 236-22.74G | |
| PEG 3350-ELECTROLYTE 420 G | |
| PEG 3350-ELECTROLYTE SOLUTION | |
| SOD SOL-POTASS SUL-MAG SUL | |
| SUFLAVE | |
| SUPREP – *Brand Co-Preferred* | |
| SUTAB | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 1 month*

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Cholestatic Pruritis

**Alagille Syndrome (ALGS):**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED (PA REQUIRED) |
|---|---|
| BYLVAY (odevixibat) | |
| LIVMARLI (maralixibat) | |

**Progressive Familial Intrahepatic Cholestasis (PFIC):**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED (PA REQUIRED) |
|---|---|
| BYLVAY (odevixibat) | LIVMARLI (maralixibat) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist.
- The member is experiencing itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member must have cholestasis, as evidenced by ≥ 1 of the following:
  - Serum bile acid > 3x upper limit of normal as defined by the reporting laboratory
  - Conjugated bilirubin > 1mg/dL
  - Fat soluble vitamin deficiency otherwise unexplainable
  - Gamma-glutamyl transferase > 3x the upper limit of normal
  - Intractable pruritus explainable only by liver disease

- The member must not have a history of liver transplant or decompensated cirrhosis.
- The member must not have history of biliary diversion surgery within the past 6 months.
- The member must have failed at least a 3-month trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Ursodiol
  - agents to treat pruritis: cholestyramine, rifampin, naltrexone
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2).*
    - The member has had a 6-month trial with Livmarli, as evidenced by paid claims or pharmacy printouts.
  - PFIC:
    - Genetic testing confirms pathogenic variant (e.g., *ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B*).
    - Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
- Livmarli Only:
  - Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*

*Renewal Criteria – Approval Duration: 12 months*
- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bilirubin < 6.5mg/dL and bile acids < 200 micromol/L

## *Clostridioides difficile*-associated diarrhea (CDAD)

### Prevention

**Fecal Microbiota**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| REBYOTA (fecal microbiota, live–jslm) SUSPENSION – *Medical Billing* | |
| VOWST (fecal microbiota spores, live-brpk) CAPSULE | |

**Monoclonal Antibody**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ZINPLAVA (bezlotaoxumab) – *Medical Billing* | |

#### *Electronic Duration Verification:*

- Vowst is payable every 6 months.

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member has one of the following (1 or 2):
  1. The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year
  2. The member has had at least one previous episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year AND one of the following
     - *C. difficile* infection was severe (defined as ZAR score ≥ 2)
     - Member is immunocompromised

## Treatment

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DIFICID (fidaxomicin) 40 MG/ML SUSPENSION | FIRVANQ (vancomycin) SOLUTION |
| DIFICID (fidaxomicin) TABLET | VANCOCIN (vancomycin) CAPSULE |
| vancomycin capsule | |
| vancomycin solution | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 1 month*

- See Preferred Dosage Form Criteria

# Crohn's Disease

## Biologic Agents

### α4 Integrin Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | TYSABRI (natalizumab) – *Medical Billing* |

++ Clinically Non-Preferred: Tysabri is associated with a risk of developing progressive multifocal leukoencephalopathy (PML), a rare, potentially fatal neurologic disease caused by reactivation of JC virus (JCV) infection.

### A4β7 Integrin Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ENTYVIO (vedolizumab) |
| | ENTYVIO (vedolizumab) – *Medical Billing* |

### Janus Kinase (JAK) Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | RINVOQ ER (upadacitinib) |

### Interleukin (IL) 12/IL-23 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SELARSDI (ustekinumab-aekn) |
| | SELARSDI (ustekinumab-aekn) – *IV Induction Medical Billing* |
| | STELARA (ustekinumab) |
| | STELARA (ustekinumab) – *IV Induction Medical Billing* |
| | STEQEYMA (ustekinumab-stba) |
| | STEQEYMA (ustekinumab-stba) -- *IV Induction Medical Billing* |
| | ustekinumab-ttwe |
| | ustekinumab-ttwe – *IV Induction Medical Billing* |
| | WEZLANA (ustekinumab-auub) |
| | WEZLANA (ustekinumab-auub) |

| | |
|---|---|
| | *– IV Induction Medical Billing* |
| | YESINTEK (ustekinumab-kfce) |
| | YESINTEK (ustekinumab-kfce)<br>*-- IV Induction Medical Billing* |

**Interleukin (IL)-23p19 Inhibitor**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | OMVOH (mirikizumab) |
| | OMVOH (mirikizumab)<br>*– IV Induction Medical Billing* |
| | SKYRIZI (risankizumab-rzaa) |
| | SKYRIZI (risankizumab-rzaa)<br>*– IV Induction Medical Billing* |

**TNF Inhibitors**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| infliximab - see Biosimilar Agents | CIMZIA (certolizumab) VIAL – *Medical Billing* |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts:

*Skyrizi Only:*
- The member has failed a 3-month trial of an TNF inhibitor, Entyvio, and a 30-day trial with Rinvoq ER, as evidenced by paid claims or printouts.

*Tysabri Only:*
- The requested medication must be prescribed by, or in consult with, a gastroenterologist

*Omvoh and Ustekinumab Only:*
- The member has failed a 3-month trial of an TNF inhibitor, Entyvio, Skyrizi, and a 30-day trial with Rinvoq ER, as evidenced by paid claims or printouts.

*Non-Preferred Biosimilars Only:*
- See Biosimilar Agents criteria

## Constipation

### *Therapeutic Duplication*

- One medication is allowed at a time.

## Chronic Idiopathic Constipation

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LINZESS (linaclotide) | AMITIZA (lubiprostone) |
| lubiprostone | MOTEGRITY (prucalopride) |
| TRULANCE (plecanatide) | prucalopride |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Motegrity:
  1. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
     - Linzess or Trulance
     - lubiprostone

## Functional Constipation

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LINZESS (linaclotide) 72 mcg | |

## Irritable Bowel Syndrome with Constipation (IBS-C)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LINZESS (linaclotide) | AMITIZA (lubiprostone) |
| lubiprostone | IBSRELA (tenapanor) |
| TRULANCE (plecanatide) | XPHOZAH (tenapanor) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Ibsrela Only:
  - The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
    - Linzess or Trulance
    - lubiprostone for members assigned female at birth
- Xphozah Only:
  - The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
    - Linzess or Trulance
    - lubiprostone for members assigned female at birth
    - Ibsrela

## Opioid-Induced Constipation

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Lubiprostone | AMITIZA (lubiprostone) |
| MOVANTIK (naloxegol) | RELISTOR (methylnaltrexone) TABLET |
| RELISTOR (methylnaltrexone) SYRINGE | |
| RELISTOR (methylnaltrexone) VIAL | |
| SYMPROIC (naldemedine) | |

### *Electronic Concurrent Medications Required*

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik, Symproic, or Relistor's date of service.
  - Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
  - Movantik
  - Symproic

## Diarrhea

### Irritable Bowel Syndrome

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| antispasmotic (e.g., dicyclomine, hyoscyamine) | alosetron |
| Loperamide | VIBERZI (eluxadoline) |
| LOTRONEX (alosetron) – *Brand Required* | XIFAXAN (rifaximin) 550 mg tablet |
| tricyclic antidepressants (e.g., amitriptyline) | |

### *Electronic Diagnosis Verification*

- Xifaxan: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Electronic Concurrent Medications Required*

- Xifaxan does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of lactulose where lactulose is not tolerated

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of a product in each preferred class, as evidenced by paid claims or pharmacy printouts.

### HIV / AIDS

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| antimotility agent (e.g., loperamide, diphenoxylate/atropine) | MYTESI (crofelemer) |
| Octreotide | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*
- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of an agent in each preferred class, as evidenced by paid claims or pharmacy printouts.

## Digestive Enzymes

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CREON (lipase/protease/amylase) | PERTZYE (lipase/protease/amylase) |
| ZENPEP (lipase/protease/amylase) | VIOKACE (lipase/protease/amylase) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- A 30-day trial of all preferred agents will be required, as evidenced by paid claims or pharmacy printouts, before a non-preferred agent will be authorized unless member stable on a pancreatic enzyme written by a gastroenterologist or pancreas disease specialist.

## Eosinophilic Esophagitis

| CLINICAL PA REQUIRED |
|---|
| DUPIXENT (dupilumab) |
| EOHILIA (budesonide) STICK PACKETS |

*Prior Authorization Criteria*

Prior Authorization Form – Eosinophilic Esophagitis

*Initial Criteria – Approval Duration: 6 months (3 months for Eohilia)*
- The requested medication must be prescribed by, or in consult with, an allergist or gastroenterologist.
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed an 8-week trial of twice daily proton pump inhibitors, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months (no renewal for Eohilia)*
- The member has achieved a significant reduction in dysphagia symptoms since treatment initiation.
- The member must have achieved an esophageal intraepithelial eosinophil count of ≤6 eos/hp.

## Ulcerative Colitis

### Biologic Agents

**α4β7 Integrin Inhibitors**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ENTYVIO (vedolizumab) |
| | ENTYVIO (vedolizumab) – *Medical Billing* |

### Interleukin (IL)-23p19 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | OMVOH (mirikizumab) |
| | OMVOH (mirikizumab)<br>*– IV Induction Medical Billing* |
| | SKYRIZI (risankizumab-rzaa) |
| | SKYRIZI (risankizumab-rzaa)<br>*– IV Induction Medical Billing* |
| | TREMFYA (guselkumab) – *Medical Billing* |
| | TREMFYA (guselkumab) |

### Interleukin (IL) 12/IL-23 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SELARSDI (ustekinumab-aekn) |
| | SELARSDI (ustekinumab-aekn)<br>*– IV Induction Medical Billing* |
| | STELARA (ustekinumab) |
| | STELARA (ustekinumab)<br>*– IV Induction Medical Billing* |
| | STEQEYMA (ustekinumab-stba) |
| | STEQEYMA (ustekinumab-stba)<br>*-- IV Induction Medical Billing* |
| | ustekinumab-ttwe |
| | ustekinumab-ttwe – *IV Induction Medical Billing* |
| | WEZLANA (ustekinumab-auub) |
| | WEZLANA (ustekinumab-auub)<br>*– IV Induction Medical Billing* |
| | YESINTEK (ustekinumab-kfce) |
| | YESINTEK (ustekinumab-kfce)<br>*-- IV Induction Medical Billing* |

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | |
| infliximab - see Biosimilar Agents | |
| SIMPONI (golimumab) | |

#### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- The member must have failed a 3-month trial of a TNF inhibitor and a 30-day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.

- Skyrizi Only: The member must have failed a 3-month trial of a TNF inhibitor and Entyvio, and a 30-day trial with a JAK inhibitor as evidenced by paid claims or pharmacy printouts.
- Omvoh and Ustekinumab Only: The member must have failed a 3-month trial of a TNF inhibitor, Entyvio, an Interleukin (IL)-23p19 Inhibitor and a 30 day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.

## 5-Aminosalicylic Acid (5-ASA)

### Oral

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| APRISO ER (mesalamine) CAPSULE<br>– *Brand Required* | AZULFIDINE (sulfasalazine) |
| balsalazide capsule | AZULFIDINE ENTAB (sulfasalazine) |
| DIPENTUM (olsalazine) | COLAZAL (balsalazide) |
| mesalamine 1.2 mg DR tablet | LIALDA (mesalamine) TABLET |
| PENTASA (mesalamine) – *Brand Required* | mesalamine ER 375 mg, 500 mg ER capsule |
| sulfasalazine DR tablet | mesalamine 400 mg DR capsule, 800 mg DR tablet |
| sulfasalazine tablet | |

### Topical

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| hydrocortisone enema | budesonide rectal foam |
| mesalamine enema | CANASA (mesalamine) SUPPOSITORY |
| mesalamine rectal suppository | mesalamine enema kit |
| | ROWASA (mesalamine) ENEMA KIT |
| | SF ROWASA (mesalamine) ENEMA |
| | UCERIS (budesonide) RECTAL FOAM |

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 3-month trial of mesalamine, as evidenced by paid claims or pharmacy printouts.
- Mesalamine HD: See Preferred Dosage Form criteria

## Janus Kinase (JAK) Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XELJANZ IR (tofacitinib) 5 mg, oral solution | RINVOQ ER (upadacitinib) |
| | XELJANZ IR (tofacitinib) 10 mg |
| | XELJANZ XR (tofacitinib) |

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Rinvoq ER Only:

- The member must have failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy printouts.

### Sphingosine 1-Phosphate (S1P) Receptor Modulator

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | VELSIPITY (etrasimod) |
| | ZEPOSIA (ozanimod) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 3-month trial of a TNF inhibitor, and 30-day trials of Xeljanz and Rinvoq ER as evidenced by paid claims or pharmacy printouts.

## Wilson's Disease

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CUPRIMINE (penicillamine) CAPSULE – *Brand Required* | CUVRIOR (trientine tetrahydrochloride) |
| DEPEN (penicillamine) TITRATAB – *Brand Required* | penicillamine capsule |
| trientine hydrochloride 250 mg | penicillamine tablet |
| | SYPRINE (trientine hydrochloride) |
| | trientine hydrochloride 500 mg |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form Criteria

# Genetic and Rare Disease

## Amyloidosis

### RNA – targeted therapies

*TTR-specific small interfering RNA (siRNA)*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ONPATTRO (patisiran) – *Medical Billing* | |

*Transhyretin-directed small interfering RNA (siRNA)*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AMVUTTRA (vutrisiran) – *Medical Billing* | |

*Antisense Oligonucleotide (ASO)*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TEGSEDI (inotersen) | |
| WAINUA (eplontersen) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- One of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., acoramidis, tafamidis)

*Renewal Criteria – Approval Duration: 12 months*

- The member has received a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%

## TTR Stabilizers

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ATTRUBY (acoramidis) | |
| VYNDAQEL (tafamidis) | |
| VYNDAMAX (tafamidis) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Confirmation of the diagnosis by both of the following must be provided:
  - presence of grade 2 or 3 positive bone tracer cardiac scintigraphy
  - absence of monoclonal protein confirmed by serum protein immunofixation, urine protein immunofixation, or serum free light chain ratio analysis
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- For Attruby only: The member must not have any of the following:

- ALT or AST > 2x ULN or Total Bilirubin >3x ULN
- NT-proBNP level > 8500 pg/mL

- The member must not have any of the following:
  - eGFR < 25 mL/min/1.73m$^2$
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, elplontersen, inotersen)

*Renewal Criteria – Approval Duration: 12 months*

- For Attruby only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT
  - NT-proBNP level
- For Vyndaqel/Vyndamax only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT
  - NYHA class

**References:**


1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.


## Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

| CLINICAL PA REQUIRED |
|---|
| BRINEURA (cerliponase alfa) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must be less than 16 years old.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist.
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1 gene.
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains.
  - Results must show a score of at least 1 in each of these domains.

*Renewal Criteria – Approval Duration: 12 months*

- The member must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection.

- The member maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The member has responded to therapy compared to pretreatment baseline with stability/lack of decline* in motor function/milestones.

  ** Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*

# Fabry Disease

## Alpha-Galactosidase A Pharmacological Chaperone

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| GALAFOLD (migalastat) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member must be assigned male at birth.
- The member's diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA) variant that is amenable to treatment with Galafold interpreted from a clinical geneticist professional
- The member must have a deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
- The medication must not be used in conjunction with enzyme replacement therapy.
- The member must not have significant renal impairment (eGFR <30 mL/minute/1.73 m2) or have had a kidney transplant

*Renewal Criteria – Approval Duration: 12 months*
- The member must have a decreased Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
  - Acroparesthesias (burning pain in the extremities)
  - Left ventricular hypertrophy (LVH)
  - Glomerular filtration rate (GFR) and/or proteinuria

## Enzyme Replacement Therapy

| CLINICAL PA REQUIRED |
|---|
| ELFABRIO (pegunigalsidase alfa) – *Medical Billing* |
| FABRAZYME (agalsidase beta) – *Medical Billing* |

*Initial Criteria – Approval Duration: 6 months*
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (A or B):
  - In males assigned at birth, must meet one of the following (1 or 2):
    1. Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    2. Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth, all of the following must be met:

- Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
- The member is experiencing one of the following symptoms:
  - Acroparesthesias (burning pain in the extremities)
  - Impaired glomerular filtration rate (GFR) or proteinuria
  - Left ventricular hypertrophy (LVH)
  - Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)
  - GL-3 deposits within the kidney

*Non-Preferred Agent Criteria:*
- The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts

*Renewal Criteria – Approval Duration: 12 months*
- The member must have a decreased urine or plasma Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
  - Acroparesthesias (burning pain in the extremities)
  - Left ventricular hypertrophy (LVH)
  - Glomerular filtration rate (GFR) and/or proteinuria
  - Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)

# Gaucher's Disease

## Enzyme Replacement Therapy

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ELELYSO (taliglucerase alfa) – *Medical Billing* | CEREZYME (imiglucerase) – *Medical Billing* |
| | VPRIV (velaglucerase alfa) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, an endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders.
- The member must have a diagnosis of Gaucher disease Type I or Type III with the one of the following:
  - Deficiency in glucocerebrosidase enzyme activity in peripheral leukocytes
  - Genetic testing confirming biallelic pathogenic variants in the GBA1 gene
- The member must be experiencing one or more of the following:
  - Low hemoglobin as reported by laboratory
  - Low platelet count (<120,000/$mm^3$)
  - Bone disease (T-score below -1.0 [DXA], height ≤ $5^{th}$ percentile for age and sex in children, bone pain or bone crisis, radiologic evidence of skeletal disease)
  - Hepatomegalsy (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size eight (8) or more times normal)

*Non-Preferred Agent Criteria:*
- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

*Renewal Criteria – Approval Duration: 12 months*

- The member has experienced a beneficial response to therapy as evidenced by normalization or significant improvement in one of the following symptoms:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dL
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone pain or crisis

### Substrate Replacement Therapy

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ZAVESCA (miglustat) – *Brand Required* | miglustat |
| **PREFERRED AGENTS (CLINICAL PA REQUIRED)** | **NON-PREFERRED AGENTS (PA REQUIRED)** |
| CERDELGA (eliglustat) | |

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- Cerdelga: See Medications that cost over $3000/month criteria

## Lysosomal Acid Lipase (LAL) Deficiency

| CLINICAL PA REQUIRED |
|---|
| KANUMA (sebelipase alfa) – *Medical Billing* |

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist.
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming 2 mutations in the LIPA gene
  - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots
- The member must have one of the following:
  - The member is ≤ 8 months old and has growth failure, severe anemia, or hepatomegaly
  - The member has an alanine aminotransferase (ALT) ≥ 1.5x upper limit of normal on 2 consecutive screenings at least one week apart.
- The member must not have had a hematopoietic stem cell or liver transplant.

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in weight for age Z-scores for individuals with growth failure, improved LDL, HDL, AST, ALT and/or triglycerides.

## Hereditary Thrombotic Thrombocytopenic Purpura (hTTP) / Congenital TTP (cTTP)

*AKA* Congenital TTP (cTTP)

| CLINICAL PA REQUIRED |
|---|
| ADZYNMA (ADAMTS13, recombinant-krhn) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: Prophylaxis: 6 months, On-Demand: 2 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist
- The diagnosis must be confirmed by both of the following:
  - genetic test confirming biallelic ADAMTS13 mutation
    - Unless member has a positive response to Adzynma inpatient and is continuing outpatient treatment, then genetic tests should be provided upon renewal
  - ADAMTS13 activity < 10% of normal with the absence of an inhibitor (i.e. ADAMTS13 autoantibodies)
- For members requesting prophylactic therapy:
  - Member must have a history of at least one of the following:
    - At least one documented TTP event
    - Member is pregnant (approval duration through 6 weeks post-partum)
  - The member must have a documented intolerance to plasma-based therapies
- For members requesting acute (On-Demand) treatment, must have an acute event defined by both of the following:
  - Platelet count < 150,000/uL or a drop in platelet count > 25% of baseline
  - Microangiopathic hemolytic anemia (LDH > 1.5 x baseline or > 1.5 x ULN)

*Renewal Criteria – Approval Duration: 12 months*

The member must have experienced a therapeutic response as evidenced by the following:

- For members receiving prophylaxis, any of the following:
  1. Decreased number of acute and subacute TTP events
  2. Increased platelet counts (within 25% of baseline or > 150,000/uL
  3. Decreased microangiopathic hemolytic anemia episodes (defined as LDH < 1.5 x baseline or < 1.5 x ULN)
- For members receiving On-Demand treatment, both of the following:
  1. Increased platelet counts (within 25% of baseline or >150,000/uL, whichever occurs first)
  2. Decreased microangiopathic hemolytic anemia (defined as LDH < 1.5 x baseline or < 1.5 x ULN)

## Alpha-Mannosidosis

| **CLINICAL PA REQUIRED** |
|---|
| LAMZEDE (velmanase alfa-tycv) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by one of the following:
  - Deficiency of alpha-mannosidase activity in leukocytes or fibroblasts < 10% of normal activity
  - Detection of biallelic pathogenic variants in the *MAN2B1* gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, a neurologist, pulmonologist, geneticist or another prescriber specializing in lysosomal storage diseases.
- The member must not have had a hematopoietic stem cell transplant.
- All of the following must be submitted:
  - Non-central nervous system manifestations (e.g., progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency)

- Elevated level of serum oligosaccharide concentration, as defined by being above the upper limit of normal by the laboratory reference range
- If 3 years of age or older, must be able to walk without support
- Motor function as measured by one of the following:
  - 6-minute walk test (6-MWT)
  - 3-minute stair climb test
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, by both of the following:
  - Reduction in serum oligosaccharide concentration
  - Stability or improvement in the one of the following scores and symptoms:
    - 6-MWT
    - 3-minute stair climb test
    - FVC via Pulmonary Function Test

# Metachromatic Leukodystrophy (MLD)

## Cell-based Gene Therapy

| CLINICAL PA REQUIRED |
|---|
| LENMELDY (atidarsagene autotemcel) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member has a diagnosis of Metachromatic Leukodystrophy (MLD), confirmed by all the following:
  - Genetic testing for biallelic ARSA pathogenic variants
  - Deficient ARSA enzyme activity in leukocytes
  - Elevated urinary excretion of sulfatides
- The member must be a child with either pre-symptomatic late infantile (PSLI) onset, pre-symptomatic early juvenile (PSEJ) onset, or early symptomatic early-juvenile (ESEJ) onset disease
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), human T-lymphotropic virus type 1 or 2 (HTLV-1 and HTLV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member must not be a recipient of a previous allogeneic transplant or gene therapy

# Mucopolysaccharidosis I (MPS I)

| CLINICAL PA REQUIRED |
|---|
| ALDURAZYME (laronidase) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:

- Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
- Deficiency in activity of the lysosomal enzyme α-L-iduronidase (IDUA) in fibroblast or leukocyte < 10% of normal activity

- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- The member's current motor function must be submitted, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test greater than 30%

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the following scores and symptoms:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

## Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

| CLINICAL PA REQUIRED |
|---|
| ELAPRASE (idursulfase) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity of ≤ 10% of the lower limit of normal in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene that leaves the Fragile X Messenger Ribonucleoprotein genes (FMR1, *FMR2*) intact
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- One of the following must be submitted:
  - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

*Renewal Criteria – Approval Duration: 12 months*

- The member must have had a therapeutic response as evidenced by improvement of one of the following:
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - 6-minute walk test (6MWT) increase
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%

## Mucopolysaccharidosis IVA (MPS IVA) – Morquio A syndrome

| CLINICAL PA REQUIRED |
|---|
| VIMIZIM (elosulfase alfa) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- Baseline Urine Keratan Sulfate (KS) levels must be submitted
- One of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, by one of the following scores:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)
  - Reduced Urine Keratan Sulfate (KS) levels

## Mucopolysaccharidosis VI (MPS VI) – Maroteaux-Lamy syndrome

| **CLINICAL PA REQUIRED** |
|---|
| NAGLAZYME (galsulfase) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of N-acetylgalactosamine 4-sufatase (arylsulfatase B or ASB) enzyme activity of <10% of the lower limit of normal
  - Detection of pathogenic variants in the ARSB gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Both of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Motor function as measured by one of the following:
    - 6 or 12-minute walk test (6-MWT or 12-MWT)
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the one of the following scores and symptoms:
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)

- Stability or improvement in 6 or 12-minute walk test (6-MWT or 12-MWT)
- Stability or improvement in 3-minute stair climb test
- Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

## Mucopolysaccharidosis VII (MPS VII) – Sly Syndrome

| CLINICAL PA REQUIRED |
|---|
| MEPSEVII (vestronidase alfa-vjbk) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of beta-glucuronidase enzyme
  - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- One or more of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being 2 or more times normal
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size 5 or more times normal)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the one of the following scores and symptoms:
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Improvement in 6-minute walk test (6MWT)
  - Improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

## Phenylketonuria

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| JAVYGTOR (sapropterin) | KUVAN (sapropterin) |
| Sapropterin | PALYNZIQ (pegvaliase-pqpz) |

### *Underutilization*

- Sapropterin and Palynziq must be used adherently and will reject on point of sale for late fill

### *Prior Authorization Criteria*

Prior Authorization Form – Phenylketonuria

*Initial Criteria – Approval Duration: 2 months (sapropterin); 12 months (Palynziq)*

- The member must have been compliant with a PHE restricted diet for past 6 months
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must meet one of the following:
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only:
  - The member's weight must be provided. Requested initial dose must be 10 mg/kg
  - The member must not have two null mutations in trans
- Palynziq Only: One of the following must be met:
  - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 3-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
  - The member is known to have two null mutations in trans

*Renewal Criteria:*

- For same or reduced dose from previous trial:
  *Approval Duration: 12 months* – if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member's weight must be provided.

- For a dose increase from previous trial
  *Approval Duration: 4 months* – for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq)
    - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member's weight must be provided.

## Pompe Disease

| PREFFERED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LUMIZYME (alglucosidase alpha) – *Medical Billing* | OPFOLDA (miglustat) *does not require PA |
| NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing* | POMBILITI (cipaglucosidase alfa-atga) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of acid alpha-glucosidase enzyme activity (2% to 40% partial deficiency of GAA non-classic infantile forms or late onset forms) of the lab specific normal mean value
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, a cardiologist, neurologist or geneticist or specialist in Pompe disease.
- The member must not have ventilation support for > 6 hours/day while awake
- The member has measurable signs of Pompe disease, such as impairment in pulmonary function or motor weakness

- Ages 5 years and older: The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
- Ages under 5 years The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
  A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  C. Hammersmith Functional Motor Scale Expanded (HFMSE)
  D. Motor Function Measure – 32 items (MFM-32)
  E. Revised Upper Limb Module (RULM)
  F. 6-minute walk test (6MWT)
- Pombiliti Only:
  - The member must have failed a 6-month trial of Lumizyme and/or Nexviazyme, as evidenced by paid claims or pharmacy printouts.
  - The member has a 6MWT ≥ 75 meters
  - The member has a sitting FVC ≥ 30% of the predicted value for healthy adults
  - Opfolda and Pombiliti must be taken concurrently

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by stabilization or improvement of the following (subject to clinical review):
  - Ages 5 years and older:
    - 6MWT and/or FVC
  - Ages under 5 years:
    - CHOP-INTEND, HINE, HFMSE, MFM-32, RULM or 6MWT scores

# Urea Cycle Agents

## Hyperammonemia

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BUPHENYL (sodium phenylbutyrate) – *Brand Required* | sodium phenylbutyrate |
| **PREFERRED AGENTS (CLINICAL PA REQUIRED)** | **NON-PREFERRED AGENTS (PA REQUIRED)** |
| PHEBURANE (sodium phenylbutyrate) | OLPRUVA (sodium phenylbutyrate) |
| | RAVICTI (glycerol phenylbutyrate) |

## N-acetylglutamate synthase (NAGS) deficiency

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CARBAGLU (carglumic acid) – *Brand Required* | carglumic acid |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Medications that cost over $3000/month criteria.

*Non-Preferred Agents Criteria:*
- See Preferred Dosage Form criteria.
- *Ravicti Only:* The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress.

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time.

# Hematology/Oncology

## Anemia

### Disease-Modifying Agents

*Telomerase Inhibitor*

| CLINICAL PA REQUIRED |
|---|
| RYTELO (imetelstat) – *Medical Billing* |

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must not have deletion 5q cytogenetic abnormality
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without TP53* mutation
- The member has transfusion-dependent anemia, defined as requiring transfusion of ≥ 4 red blood cell units over an 8-week period despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half from baseline
    - Complete transfusion independence

*TGF-Beta Signaling Modulator*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| REBLOZYL (luspatercept) – *Medical Billing* |

*Initial Criteria – Approval Duration: 6 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must not have deletion 5q cytogenetic abnormality
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.

*For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm*:
- The member must require 2 or more RBC units over an 8-week period in the past 3 months
- The member has ring sideroblasts ≥ 5% or a mutated SF3B1 gene
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without TP53* mutation
- The member must meet one of the following:
  - Serum erythropoietin greater than 200 mU/mL
  - Serum erythropoietin less than or equal to 200 mU/mL with an inadequate response to ESA (defined as hemoglobin of less than 11 g/dL or continued need for transfusions) despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

*For anemia due to beta thalassemia:*
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks.
- The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks.

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- Dose will be increased to 1.25 mg/kg daily if renewal criteria has not been met.

## Cell-based Gene Therapy

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CASGEVY (exagamglogene autotemcel) – *Medical Billing* | ZYNTEGLO (betibeglogene autotemcel) – *Medical Billing* |

*Initial Criteria – Approval Duration: 12 months*
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or prescriber specializing in the treatment of beta thalassemia
- For members older than 35 years old, clinical justification must be provided (including ability to provide minimum cells required for manufacturing), subject to clinical review.
- Diagnosis should be confirmed with a non-ß0/ß0 or ß0/ß0 genotype via genetic testing
- The member must have a transfusion-dependent beta thalassemia requiring one of the following:
  - At least 100 mL/kg/year of packed red blood cells (pRBCs) in the preceding 2 years
  - At least 8 transfusions of pRBCs per year in the preceding 2 years
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- The member must not be a recipient of a previous allogeneic transplant or gene therapy

- The member must not have a matched allogeneic transplant donor.
- Member must not have any of the following:
  - Severely elevated iron in the heart as evidenced by any of the following:
    - Cardiac T2* < 10 msec by MRI
    - LVEF < 45%
  - Advanced liver disease as evidenced by any of the following:
    - AST or ALT > 3 times the upper limit of normal
    - Direct bilirubin value > 2.5 times the upper limit of normal
    - Liver iron content ≥ 15 mg/g (per MRI) with liver biopsy, VCTE, ELF, or MRE demonstrating bridging fibrosis or cirrhosis

# Chelating Agents

## Iron Chelators

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| deferasirox tablet for suspension | EXJADE (deferasirox tablet for suspension) |
| deferasirox tablet | deferasirox sprinkle |
| deferoxamine mesylate vial – *Medical Billing* | DESFERAL (deferoxamine) MESYLATE VIAL – *Medical Billing* |
| | FERRIPROX (deferiprone) |
| | JADENU (deferasirox) SPRINKLE |
| | JADENU (deferasirox) TABLET |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

# Cold Agglutin Disease (CAD)

### *Anti-B-cell Therapy*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab - see Biosimilar Agents | |

### *Anti-Complement Therapy*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ENJAYMO (sutimlimab-jome) – *Medical Billing* |

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d

- Cold agglutinin titer ≥ 64 at 4°C
- Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- The member has a baseline hemoglobin level ≤ 10 g/dL
- The member has a baseline bilirubin level above normal reference range of the reporting laboratory
- The member has one or more of the following symptoms:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud's phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event
- The member must have been unresponsive to previous rituximab-based therapy or one of the following must be documented:
  - Member has a medical reason why rituximab-based therapy is not appropriate or is contraindicated.
  - Member has severe anemia or acute exacerbations of hemolysis and needs a bridge therapy awaiting the effects of a rituximab-based therapy.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have had a therapeutic response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by ≥ 2 g/dL from baseline or Hgb level ≥ 12 g/dL
  - Normalization of bilirubin levels to less than 1.2 mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab.

## Cytokine Release Syndrome

### Interleukin (IL) -6 Receptor Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Medications that cost over $3000/month criteria

## Hemophagocytic Lymphohistiocytosis (HLH)

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| GAMIFANT (emapalumab-lzsg) – *Medical Billing* |

*Initial Criteria – Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist.
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant.
- Confirmation of the diagnosis must be submitted, as evidenced by the following:

- Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)
- Confirmation of 5 of the following clinical characteristics:
  - Fever ≥ 101.3F for over 7 days
  - Splenomegaly
  - Two of the following cytopenias in the peripheral blood:
    - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
    - Platelet count < 100,000/microL
    - ANC <1000/microL
  - One of the following:
    - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
    - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L
  - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
  - Low or absent natural killer cell activity
  - Ferritin ≥ 500 mg/L
  - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL

- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

**Category Criteria (Renewal):** *Approval Duration: 3 months or up to the HSCT date*

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

# Hemophilia

## Clotting Factor Products

### Hemophilia A

#### Factor VIII – Non-Extended Half Life

*Plasma Derived*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HEMOFIL M (factor VIII plasma derived; mAb-purified) | |
| KOATE (factor VIII plasma derived, chromatography purified) | |

*First Generation – Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | RECOMBINATE (factor VIII recombinant) |

*Second Generation – Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KOGENATE FS (factor VIII recombinant) | |

*Third Generation – Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NOVOEIGHT (factor VIII recombinant) | ADVATE (factor VIII recombinant) |
| KOVALTRY (factor VIII recombinant) | |
| XYNTHA (factor VIII recombinant) | |
| XYNTHA SOLOFUSE (factor VIII recombinant) | |

*Fourth Generation – Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AFSTYLA (factor VIII recombinant, single chain) | |
| NUWIQ (factor VIII recombinant) | |

**Factor VIII Extended Half Life**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ADYNOVATE (factor VIII recombinant, PEGylated) | ELOCTATE (factor VIII recombinant, Fc fusion protein) |
| ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) | ESPEROCT (factor VIII recombinant, glycoPEGylated – exei) |
| JIVI (factor VIII recombinant, pegylated-aucl) | |

**Recombinant humanized bispecific monoclonal antibody**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HEMLIBRA (emicizumab-kxwh) | |

**Tissue Factor Pathway Inhibitor (TFPI) Antagonist**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ALHEMO (concizumab-mtci) |
| | HYMPAVZI (marstacimab-hncq) |

## Factor VII deficiency or Hemophilia A and B with Inhibitors

*Factor VIIa*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NOVOSEVEN RT (coagulation Factor VIIa recombinant) | |
| SEVENFACT (coagulation Factor VIIa recombinant) | |

*B domain-deleted porcine – Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII) | |

## Hemophilia B

**Factor IX – Non-Extended Half Life**

*Plasma Derived*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALPHANINE SD (factor IX, plasma-derived) | |
| MONONINE (factor IX, plasma-derived mAb purified) | |

*Recombinant*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BENEFIX (factor IX recombinant) | |
| IXINITY (factor IX recombinant) | |
| RIXUBIS (factor IX recombinant) | |

**Factor IX – Extended Half Life**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALPROLIX (factor IX recombinant, Fc fusion) | |

| | |
|---|---|
| IDELVION (factor IX recombinant, albumin fusion) | |
| REBINYN (factor IX recombinant, glycol-PEGylated) | |

**Tissue Factor Pathway Inhibitor (TFPI) Antagonist**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ALHEMO (concizumab-mtci) |
| | HYMPAVZI (marstacimab-hncq) |

**Prothrombin Complex Concentrates**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FEIBA NF (Anti-Inhibitor coagulant complex) | |
| KCENTRA (hum prothrombin cplx(PCC)4fact) | |
| PROFILNINE (factor IX cplx(pcc)no4,3factor) | |

## Von Willebrand disease

**Factor VIII/vWF**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human)) | |
| HUMATE-P (factor VIII/von Willebrand Factor (human)) | |
| WILATE (factor VIII/von Willebrand Factor (human)) | |

**Von Willebrand Factor**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| VONVENDI (recombinant human vWF) | |

## Factor X Deficiency

**Factor X – Plasma Derived**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| COAGADEX (coagulation factor X (human)) | |

## Factor XIII Deficiency

**Factor XIII – Plasma Derived**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CORIFACT (factor XIII concentrate (human)) | |

**Factor XIII A – Subunit, Recombinant**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TRETTEN (Factor XIII A-Subunit, recombinant) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.

- The contact information for Hemophilia Treatment Center must be provided.

*Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).
- The member may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

## Gene Therapy

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| BEQVEZ (fidanacogene elaparvovec-dzkt) – *Medical Benefit Only* |
| HEMGENIX (etranacogene dezaparvovec) – *Medical Benefit Only* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The Medicaid Member must meet FDA-approved label for use
- The member has completed Factor IX inhibitor testing demonstrating the absence of a Factor IX inhibitor
- The member has completed liver health assessment including all of the following:
  - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin
  - Hepatic ultrasound and elastography
  - In case of patients with either radiological liver abnormalities or sustained liver enzyme elevations, a consulting hepatologist has assessed the that the member is eligible to receive the gene therapy
- Beqvez Only:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
  - The requested medication must be prescribed by, or in consult with, a hematologist at a dose of 5 × 1011 vector genomes per kg (vg/kg) of body weight.
  - The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
  - The contact information for Hemophilia Treatment Center must be provided.
  - The member was assigned male at birth.
  - The member must currently be treated with routine Factor IX prophylaxis therapy for at least 12 months.
  - The member must have had a life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
  - The member has had HIV testing that confirms that member does not have a CD4+ cell count <200 $mm^3$ or viral load ≥20 copies/mL
  - Clinical justification must be provided why Hemgenix cannot be used (subject to clinical review)

# Hematopoietic, Colony Stimulating Factors

## Filgrastim

### *Medical Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| filgrastim – See Biosimilar Agents | |

## Pegfilgrastim

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pegfilgrastim – See Biosimilar Agents | |

## Sargramostim

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LEUKINE (sargramostim) | |
| LEUKINE (sargramostim) – *Medical Billing* | |

## Eflapegrastim-xnst

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ROLVEDON (eflapegrastim-xnst) |
| | ROLVEDON (eflapegrastim-xnst) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form criteria.

# Nausea/Vomiting

## Chemo-Induced

## NK1 Receptor Antagonists

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| aprepitant tripack | AKYNZEO (netupitant/palonosetron) CAPSULE |
| EMEND (aprepitant) SUSPENSION | aprepitant capsules |
| | EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK |
| | EMEND (aprepitant) CAPSULES |

## 5-HT3 Receptor Antagonists

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| granisetron tablet | AKYNZEO (netupitant/palonosetron) CAPSULE |
| granisetron vial – *Medical Billing* | SANCUSO (granisetron) PATCH |
| SUSTOL (granisetron) SYRINGE – *Medical Billing* | ZOFRAN (ondansetron) |

## Cannabinoids

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dronabinol capsule | MARINOL (dronabinol) CAPSULE |

### *Electronic Diagnosis Verification*

- Dronabinol Only: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months or until last day of chemotherapy*

- The requested medication must be prescribed by, or in consult with, an oncologist.
- The member must be receiving a moderately or highly emetogenic chemotherapy.
- The final date of chemotherapy treatment must be provided with the request.
- The member must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months, as evidenced by paid claims or pharmacy printouts.
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects.

## Paroxysmal Nocturnal Hemoglobinuria (PNH)

### C5 inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ULTOMIRIS (ravulizumab) | PIASKY (crovalimab-akkz) – *Medical Billing* |
| ULTOMIRIS (ravulizumab) – *Medical Billing* | SOLIRIS (eculizumab) – *Medical Billing* |

### C3 Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EMPAVELI (pegcetacoplan) | |

### Factor B Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | FABHALTA (iptacopan) |

### Factor D Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | VOYDEYA (danicopan) |

### *Prior Authorization Criteria*

Prior Authorization Form – Paroxysmal Nocturnal Hemoglobinuria

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a hematologist.
- Diagnosis must be confirmed by flow cytometry demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (e.g., CD55, CD59)
- One of the following criteria must be met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%
    - hemoglobin < 10 g/dL
    - LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

*Non-Preferred Agent Criteria:*

*Fabhalta Only:*

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%
    - hemoglobin < 10 g/dL
    - LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Voydeya Only:

- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Piasky and Soliris Only:

- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

*<u>Renewal Criteria – Approval Duration:</u> 12 months*

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following:
  - Member has not required transfusion in the past 6 months
  - Increase in hemoglobin by ≥ 2 g/dL from baseline
  - Normal LDH levels ≤ 280 U/L

*Non-Preferred Agent Criteria:*

Fabhalta Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Empaveli.

Voydeya Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Ultomiris.

Piasky and Soliris Only:

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris with Voydeya

**References:**

1. Parker, Charles J. “Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria.” Hematology 2014, the American Society of Hematology Education Program Book 2016.1 (2016): 208-216.

## Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

| CLINICAL PA REQUIRED |
|---|
| RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level ≤ 45% *(If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)*
  - Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  - Genetic testing to confirm biallelic pathogenic *PLG* mutation

*Renewal Criteria – Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request*

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, subject to clinical review, including the following:
  - The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  - Trough plasminogen activity levels are >10% above baseline.

## Sickle Cell Disease

### Disease-Modifying Agents

#### *First Line Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DROXIA (hydroxyurea) capsule | HYDREA (hydroxyurea) CAPSULE |
| hydroxyurea capsule | SIKLOS (hydroxyurea) tablet |

#### *Second Line Agents*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ENDARI (glutamine) – *Brand Required* | +ADAKVEO (crizanlizumab-tmca) – *Medical Billing* |
| | L-glutamine |

+ Based on results of the STAND clinical trial, the efficacy of Adakveo in the prevention of vaso-occlusive crisis (VOC) is unclear.

#### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.

- The member has experienced at least one sickle cell-related VOC within past 12 months while adherent with hydroxyurea (documentation required) at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- Adakveo Only:
  - The member must have had a 30-day trial of a Endari, as evidenced by paid claims or pharmacy printouts.
- Siklos Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - See Preferred Dosage Form Criteria

*Renewal Criteria – Approval Duration: 12 months*

- Adakveo Only:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, subject to clinical review, by the reduction in sickle cell-related VOCs
- All Other Products:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, subject to clinical review, by one of the following:
    - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
    - Decrease in indirect bilirubin from baseline
    - Decrease in percent reticulocyte count from baseline
    - Reduction in sickle cell-related vaso-occlusive crisis

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XROMI (hydroxyurea) | |

## Cell-based Gene Therapy

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| CASGEVY (exagamglogene autotemcel) – *Medical Billing* |
| LYFGENIA (lovotibeglogene autotemcel) – *Medical Billing* |

*Initial Criteria – Approval Duration: 12 months*

- The member is ≥ 12 and ≤ 50 years of age
- The member has a diagnosis of sickle cell disease (SCD), with either βS/βS or βS/β0 or βS/β+ genotype
- The member has experienced at least four (4) sickle cell-related VOCs or priapism within past 24 months that required pain medications or RBC transfusion at a medical facility while on hydroxyurea at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member does not have inadequate bone marrow function, as defined by an absolute neutrophil count of < 1000/µL (< 500/µL for members on hydroxyurea treatment) or a platelet count < 100,000/µL
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member must not have a matched allogeneic transplant donor.

*Lyfgenia Only:*

- The member must not have more than two α-globin gene deletions (−α3.7/−α3.7)

# Thrombocytopenia

## Immune Thrombocytopenic Purpura (ITP)

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NPLATE (romiplostim) | ALVAIZ (eltrombopag choline) |
| PROMACTA (eltrombopag) | DOPTELET (avatrombopag) |
| PROMACTA (eltrombopag) POWDER PACK | TAVALISSE (fostamatinib) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 4 months*

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >3 months.
- The member has a platelet count of less than 30 x $10^9$/L
- The member must have experienced an inadequate response after one of the following (A, B or C):
  A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy printouts.
  B. Rituximab
  C. The member must have undergone a splenectomy.

*Non-Preferred Agents Criteria:*

- The member must have failed trials with eltrombopag (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- The member has a platelet count greater than or equal to 50 x $10^9$/L

**References:**


1. Neunert, Cindy, et al. “American Society of Hematology 2019 guidelines for immune thrombocytopenia.” *Blood advances* 3.23 (2019): 3829-3866.


## Chronic Liver Disease-Associated Thrombocytopenia

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DOPTELET (avatrombopag) | MULPLETA (lusutrombopag) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: The 2 weeks prior to procedure*

- The member must have platelet count of less than 50 x $10^9$/L
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding
- The scheduled date of procedure, and date therapy will be initiated and discontinued has been submitted:
  - Doptelet: Member must undergo procedure 5-8 days after last dose.
  - Mulpleta: Member must undergo procedure 2-8 days after last dose.

*Non-Preferred Agents Criteria:*

- The member must have failed trials with the preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

## Chronic Hepatitis C Infection-Associated Thrombocytopenia

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| PROMACTA (eltrombopag) | ALVAIZ (eltrombopag choline) |
| PROMACTA (eltrombopag) POWDER PACK | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 4 months*
- The member is unable to receive direct acting antivirals for hepatitis C.
- The member's degree of thrombocytopenia must prevent initiation or continuation of interferon-based therapy.

*Renewal Criteria – Approval Duration: 12 months*
- The member has a platelet count greater than or equal to 50 x $10^9$/L
- The member is currently receiving interferon-based therapy.

## Aplastic Anemia

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| PROMACTA (eltrombopag) | ALVAIZ (eltrombopag choline) |
| PROMACTA (eltrombopag) POWDER PACK | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 4 months*
- The member must have platelet count of less than 30 x $10^9$/L
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine)

*Renewal Criteria – Approval Duration: 12 months*
- The member has a platelet count greater than or equal to 50 x $10^9$/L

# Hepatology

## Metabolic Dysfunction-Associated Steatohepatitis (MASH)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pioglitazone | REZDIFFRA (resmetirom) |
| VICTOZA (liraglutide) | OZEMPIC (semaglutide) |
| | SAXENDA (liraglutide) |
| | WEGOVY (semaglutide) |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*
- The requested medication must be prescribed by, or in consult with, an endocrinologist, gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).

5. Magnetic resonance elastography (MRE)

- If the member has a history of alcohol use within the past 5 years, one of the following must be met:
  1. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  2. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- Rezdiffra Only:
  - If concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide combined with pioglitazone as evidenced by paid claims or pharmacy printouts
  - If no concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide as evidenced by paid claims or pharmacy printouts.
- Saxenda Only:
  - If the member qualifies for Saxenda, the most cost effective liraglutide product will be authorized.
- Wegovy Only:
  - If the member qualifies for Wegovy, a dose escalation to 2mg weekly of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced one of the following (1-3):
  1. Resolution of steatohepatitis AND no worsening of liver fibrosis
  2. Improvement of liver fibrosis greater than or equal to one stage AND no worsening of steatohepatitis
  3. Both resolution of steatohepatitis AND improvement in fibrosis.
- Fibrosis and steatosis are measured by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
  5. Magnetic resonance elastography (MRE)

## Primary Biliary Cholangitis

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ursodiol tablets | IQIRVO (elafibranor) |
| | LIVDELZI (seldelpar lysine) |
| | OCALIVA (obeticholic acid) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in cons ult with, a hepatologist or a gastroenterologist
- The diagnosis must be confirmed by liver biopsy
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- The member must not have a history of decompensated cirrhosis
- The member must have failed at least a 6-month trial of ursodiol, as evidenced by paid claims or pharmacy printouts, as evidenced by one of the following
  - ALP > 1.67 x Upper Limits of Normal (ULN) as defined by reporting laboratory
  - Bilirubin > ULN

- If the member has a history of alcohol use within the past 5 years, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

*Renewal Criteria – Approval Duration: 12 months*

- The member has experienced a therapeutic response as evidenced by one of the following (A or B):
  A. Both of the following (1 or 2):
     1. ALP < 1.67 x ULN OR > 15% decrease in ALP from baseline
     2. Total bilirubin is less than ULN

The member is currently on Livdelzi and is receiving itch benefit and has had previous trials of cholestyramine, rifampin, and naltrexone that did not provide itch relief.

# Infectious Disease

## Anti-infectives – COVID-19

| PREFERRED AGENTS (NO PA REQUIRED) |
|---|
| PAXLOVID (nirmatrelvir/ritonavir) |

*Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

## Anti-infectives – Resistance Prevention

### Antifungals – Aspergillus and Candidiasis Infections

*Solid Dosage Form*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| clotrimazole | CRESEMBA (isavuconazonium) |
| clotrimazole troche | DIFLUCAN (fluconazole) |
| fluconazole | NOXAFIL (posaconazole) |
| itraconazole | SPORANOX (itraconazole) |
| nystatin | VFEND (voriconazole) |
| ORAVIG (miconazole) | |
| posaconazole | |
| terbinafine | |
| voriconazole | |

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fluconazole suspension | DIFLUCAN (fluconazole) SUSPENSION |
| itraconazole solution | NOXAFIL (posaconazole) POWDERMIX SUSPENSION |
| NOXAFIL (posaconazole) SUSPENSION | SPORANOX (itraconazole) SOLUTION |
| | TOLSURA (itraconazole) DISPERSE CAPSULE |

| | |
|---|---|
| | voriconazole suspension |

## Community-Acquired Pneumonia

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amoxicillin | BAXDELA (delafloxacin) |
| amoxicillin-clavulanate | FACTIVE (gemifloxacin) |
| azithromycin | XENLETA (lefamulin) |
| cefpodoxime | |
| cefuroxime | |
| clarithromycin | |
| doxycycline | |
| levofloxacin | |
| linezolid | |
| moxifloxacin | |

## Cytomegalovirus infection

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| valganciclovir | LIVTENCITY (maribavir) |

## Methicillin-Resistant *Staphylococcus aureus* (MRSA):

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| clindamycin | BAXDELA (delafloxacin) |
| doxycycline | NUZYRA (omadacycline) |
| linezolid | SIVEXTRO (tedizolid) |
| minocycline | |
| trimethoprim-sulfamethoxazole | |

## *Helicobacter pylori*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| lansoprazole/amoxicillin/clarithromycin | bismuth subcitrate potassium/metronidazole/tetracycline |
| PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline) – *Brand Required* | OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin) |
| | TALICIA (omeprazole/amoxicillin/rifabutin) |
| | VOQUEZNA DUAL PAK (vonoprazan/amoxicillin) |
| | VOQUEZNA TRIPLE PAK (vonoprazan/amoxicillin/clarithromycin) |

## *Tuberculosis*

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED AGENTS (PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| ethambutol | isoniazid | cycloserine |
| PRIFTIN (rifapentine) | | MYCOBUTIN (rifabutin) |
| pyrazinamide | | RIFADIN (rifampin) |
| rifabutin | | SIRTURO (bedaquiline) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 5 days or as supported in compendia for indication*

- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic/antifungal stewardship program, or protocol.
- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - For Voquezna Dual or Triple Pak – member must have a clarithromycin or amoxicillin resistant strain of *H. Pylori*)
- One of the following criteria must be met (A or B):
  A. The member is continuing treatment upon discharge from an acute care facility.
  B. Clinical justification must be provided explaining why the preferred antibiotics/antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

*Tuberculosis Only:*
- Isoniazid: The ND Division of Disease Control Tuberculosis Prevention and Control program provides isoniazid for no cost through the UND Center for Family Medicine Pharmacy. Please contact 701-328-2378 to obtain supply.

*Renewal Criteria – Approval Duration: 5 days*
- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

# Human Immunodeficiency Virus (HIV)

## Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| APRETUDE (cabtegravir) | TRUVADA (emtricitabine/tenofovir disoproxil fumarate) |
| DESCOVY (emtricitabine/tenofovir alafenamide) | |
| emtricitabine/tenofovir disoproxil fumarate | |

## Antiretrovirals – Treatment

**References:**

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf Accessed (October 9, 2020)

### Integrase Strand Transfer Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BIKTARVY (bictegravir/emtricitabine/tenofovir) | |
| CABENUVA (cabotegravir/rilprivirine) *– Medical Billing* | |
| DOVATO (dolutegravir/lamivudine) | |

| | |
|---|---|
| GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir) | |
| ISENTRESS (raltegravir) | |
| JULUCA (dolutegravir/rilpivirine) | |
| STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir) | |
| TIVICAY (dolutegravir) | |
| TRIUMEQ (abacavir/dolutegravir/lamivudine) | |
| TRIUMEQ PD (abacavir/dolutegravir/lamivudine) | |

## Non-Nucleoside Reverse Transcriptase Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| COMPLERA (emtricitabine/rilpivirine/tenofovir) | ATRIPLA (efavirenz/emtricitabine/tenofovir) |
| efavirenz | EDURANT (rilpivirine) |
| efavirenz/emtricitabine/tenofovir | efavirenz/lamivudine/tenofovir |
| JULUCA (dolutegravir/rilpivirine) | rilpivirine |
| ODEFSEY (emtricitabine/rilpivirine/tenofovir) | |
| PIFELTRO (doravirine) | |
| SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required* | |
| SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required* | |
| **Not Recommended for First Line Use** | |
| etravirine | INTELENCE (etravirine) |
| nevirapine | nevirapine ER |

- Etravirine – Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.
- Nevirapine – Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration:* 12 months

- See Preferred Dosage Form criteria

## Nucleoside Reverse Transcriptase Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| abacavir | ATRIPLA (efavirenz/emtricitabine/tenofovir) |
| abacavir/lamivudine | efavirenz/lamivudine/tenofovir |
| BIKTARVY (bictegravir/emtricitabine/tenofovir) | emtricitabine capsule |
| CIMDUO (lamivudine/tenofovir) | EMTRIVA (emtricitabine) CAPSULE |
| COMPLERA (emtricitabine/rilpivirine/tenofovir) | EPIVIR (lamivudine) |
| DELSTRIGO (doravirine/lamivudine/tenofovir) | lamivudine |

| | |
|---|---|
| DESCOVY (emtricitabine/tenofovir alafenamide) | TRIZIVIR (abacavir/lamivudine) |
| efavirenz/emtricitabine/tenofovir | TRUVADA (emtricitabine/tenofovir disoproxil fumarate) |
| emtricitabine solution | VIREAD (tenofovir) |
| emtricitabine/tenofovir disoproxil fumarate | ZIAGEN (abacavir) |
| GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir) | |
| ODEFSEY (emtricitabine/rilpivirine/tenofovir) | |
| SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required* | |
| SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required* | |
| STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir) | |
| SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir) | |
| tenofovir | |
| TEMIXYS (lamivudine/tenofovir) | |
| TRIUMEQ (abacavir/dolutegravir/lamivudine) | |
| TRIUMEQ PD (abacavir/dolutegravir/lamivudine) | |
| **Not Recommended for First Line Use** | |
| abacavir/lamivudine/zidovudine | RETROVIR (zidovudine) |
| didanosine | TRIZIVIR (abacavir/lamivudine/zidovudine) |
| lamivudine/zidovudine | ZERIT (stavudine) CAPSULE |
| stavudine | zidovudine capsule and tablet |
| zidovudine syrup | |

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine **–** Guidelines do not recommend ddl/3TC or ddl/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddl toxicities (including pancreatitis and peripheral neuropathy). Ddl/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddl drug exposure and toxicities.
- lamivudine/zidovudine **–** Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration:* 12 months

- See Preferred Dosage Form criteria

## Post-Attachment Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| TROGARZO (Ibalizumab-uiyk) | |

## Protease Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Atazanavir | NORVIR (ritonavir) |
| Darunavir | PREZISTA (darunavir) |
| EVOTAZ (atazanavir/cobicistat) | REYATAZ (atazanavir) |
| NORVIR (ritonavir) POWDER PACKET | |
| PREZCOBIX (darunavir/cobicistat) | |
| REYATAZ (atazanavir) POWDER PACK | |
| Ritonavir | |
| SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir) | |
| **Not Recommended for First Line Use** | |
| APTIVUS (tipranavir) | KALETRA (lopinavir/ritonavir) |
| Fosamprenavir | |
| INVIRASE (saquinavir) | |
| lopinavir/ritonavir | |
| VIRACEPT (nelfinavir) | |

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted Pis.
- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.
- Saginavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high bill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted Pis.

## Capsid Function Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| **Not Recommended for First Line Use** | |
| SUNLENCA (lenacapavir) INJECTION – *Medical Billing* | |
| SUNLENCA (lenacapavir) TABLET | |

- lenacapavir – SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| **Not Recommended for First Line Use** | |
| FUZEON (enfuvirtide) | |
| SELZENTRY (maraviroc) | |

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure

- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

## Diarrhea

Mytesi – See Diarrhea criteria

## Loss of Appetite

Dronabinol: See Nausea/Vomiting criteria

## Wasting Cachexia

Serostim: See Growth Hormone criteria

# Hepatitis C Antiviral Treatments

## Direct Acting Antivirals

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| sofosbuvir/velpatasvir | EPCLUSA (sofosbuvir/velpatasvir) |
| | HARVONI (ledipasvir/sofosbuvir) |
| | ledipasvir/sofosbuvir 90mg/400mg tablet |
| | MAVYRET (glecaprevir/pibrentasvir) |
| | SOVALDI (sofosbuvir) |
| | VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir) |
| | ZEPATIER (elbasvir/grazoprevir) |

### *Electronic Concurrent Medication Required*

- Epclusa (and its generic): A total of 84 days of ribavirin must be billed within the previous 14 days of a sofosbuvir/velpatasvir claim if member has decompensated cirrhosis (Child Pugh B or C).

### *First Fill*

- Epclusa (and its generic) and Vosevi: The entire treatment course must be dispensed at the initial fill.
    A. Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

### *Prior Authorization Criteria*

Prior Authorization Form – Hepatitis C

*Initial Criteria – Approval Duration: Based on label recommendations*

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
    1. The member has no history of alcohol use disorder or IV illicit drug use.
    2. The member has maintained sobriety for the past 12 months.
    3. The member has completed or be currently enrolled in a treatment program within the past 12 months.

4. The Harm Reduction Program Participation Attestation Form is attached indicating one of the following (a or b):
   a. The member participates in a Syringe Service Program
   b. The member participates in at least 2 Harm Reduction Pathway appointments as defined in Appendix D (may be completed by any qualified healthcare provider)

*Non-Solid Dosage Form Agents Criteria:*

- Harvoni and Sovaldi pellets: The member must weigh less than 17 kg or be less than 3 years old.
- Mavyret pellets: All of the following are met (A and B):
  A. The member must be 3 years old or greater
  B. The member must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria
- Epclusa pellets: All of the following are met (A, B, and C)
  A. The member must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria
  B. The member is unable to use Mavyret pellets

*Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

**For FIRST TIME or RE-INFECTION Treatment with Direct Acting Antivirals or incomplete therapy after receiving < 28 days:**

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
  - No liver fibrosis or unknown (one of the following):
    - 2 positive HCV RNA levels at least 3 months apart
    - 1 positive HCV RNA test with the last likely HCV exposure occurring at least 6 months before the most recent positive test
  - Liver fibrosis or cirrhosis:1 positive HCV RNA test
- For incomplete therapy, the following criteria is met:

| | |
|---|---|
| **Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)** | The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days.<br><br>Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner). |

**For RE-TREATMENT after Direct Acting Antiviral failure or incomplete therapy after receiving ≥ 28 days:**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ribavirin | MAVYRET (glecaprevir/pibrentasvir) |
| VOSEVI (sofosbuvir/velpatasvir/voxilaprevir) | SOVALDI (sofosbuvir) 400MG TABLET |

- The requested medication must be prescribed by, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)
- Chronic Hepatitis C must be documented by 1 HCV RNA test since most recent DAA treatment (HCV RNA level must be within the last 24 months)
- The following criteria is met (as applicable due to reason for retreatment):

| Reason for retreatment: | |
|---|---|
| **Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)** | The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days.<br><br>Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner). |
| **Resistance** | • **FIRST TIME treatment with Direct Acting Antivirals** criteria must be met |

*Non-Preferred Agents Criteria:*

- The member has had a failed treatment course with Vosevi.

## Influenza

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| oseltamivir | TAMIFLU (oseltamivir) |
| | XOFLUZA (baloxavir marboxil) |

### *Electronic Age Verification*

- Xofluza: The member must be 5 years of age or older

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 5 days*

- The member must have failed a 5-day trial of oseltamivir, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

## Malaria

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| hydroxychloroquine | atovaquone/proguanil |
| quinine | chloroquine |
| | COARTEM (artemether/lumefantrine) |
| | KRINTAFEL (tafenoquine) |
| | MALARONE (atovaquone/proguanil) |
| | mefloquine |
| | primaquine |
| | QUALAQUIN (quinine) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 7 days*

- The member must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The request must be for treatment of malaria (*NOT covered for prophylaxis*)

# Respiratory Syncytial Virus (RSV) Prophylaxis

| CLINICAL PA REQUIRED |
| --- |
| SYNAGIS (palivizumab) – *Medical Billing* |

## *Prior Authorization Criteria*

Prior Authorization Form – RSV Prophylaxis

*Initial Criteria – Approval Duration: Up to 5 weight-based doses within 6 months of season onset. No further prior authorization requests will be approved following season offset. An SA will only be approved until age 2 or through the second season, whichever occurs first.*

*Respiratory Syncytial Virus (RSV) Season defined as onset (1st of 2 consecutive weeks when percentage of PCR tests positive for RSV is > 3% and offset (Last of 2 consecutive weeks when percentage of PCR tests positive for RSV is < 3%) as reported by The National Respiratory and Enteric Virus Surveillance System (NREVSS) Region 8* Interactive Dashboard | NREVSS | CDC
*North Dakota data specific data is available at: Respiratory Syncytial Virus (RSV) | Health and Human Services North Dakota*

*If a post-season spike occurs (defined as season onset criteria met within 3 months of season offset), infants may be approved for doses until the age of 3 months old if they meet clinical criteria and have not already received 5 doses during the defined season.*

- Clinical justification must be provided addressing why nirsevimab could not be given from VFC (subject to clinical review)
- The member had not received another monoclonal antibody for RSV prophylaxis during the current RSV season.
- The member must not have received immunity through a maternal Respiratory Syncytial Virus Vaccine.
- The member must have one of the following diagnoses and the additional criteria outlined for diagnosis:
  - **Prematurity:**
    - < 29 weeks, 0 days gestational age
      - ≤ 12 months of age at start of RSV season
    - ≥ 29 weeks, 0 days gestational age to ≤ 35 weeks, 0 days gestational age
      - ≤ 6 months of age at start of RSV season
      - One of the following:
        - Neuromuscular disease or pulmonary abnormality that impairs ability to clear secretions from the upper airway because of ineffective cough
        - Profoundly immunocompromised receiving chemotherapy, solid organ transplantation, hematopoietic stem cell transplantation, or require colony stimulating factors
  - **Chronic Lung Disease of Prematurity (CLD)**
    - < 32 weeks, 0 days gestational age
      - ≤12 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - < 32 weeks, 0 days gestational age
      - 13-24 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
      - Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
  - **Congenital Heart Disease**
    - ≤12 months of age at start of RSV season

- Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

**References:**


1. American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics; July 2022. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/
2. Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. J Infect Dis 2017;216:345–55
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4external icon


# Nephrology/Urology

## Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

| CLINICAL PA REQUIRED |
|---|
| SOLIRIS (eculizumab) – *Medical Billing* |
| ULTOMIRIS (ravulizumab-cwvz) |
| ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist.
- The member has all the following:
  - Low platelet count, as defined by laboratory reference range or member requires dialysis.
  - Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.
  - Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.
- The member does not have bloody diarrhea.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range.
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

## Benign Prostatic Hyperplasia

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| alfuzosin ER | AVODART (dutasteride) |
| CARDURA XL (doxazosin) | CARDURA (doxazosin) |

| | |
|---|---|
| doxazosin | ENTADFI (finasteride/tadalafil) |
| dutasteride | FLOMAX (tamsulosin) |
| finasteride | MINIPRESS (prazosin) |
| prazosin | PROSCAR (finasteride) |
| silodosin | RAPAFLO (silodosin) |
| tamsulosin | sildenafil |
| terazosin | tadalafil |

### *Electronic Diagnosis Verification*

- Finasteride, sildenafil, and tadalafil: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Sildenafil/tadalafil: Documentation (e.g., chart notes) must be provided confirming the diagnosis.

## Chronic Kidney Disease

### *Therapeutic Duplication*

- Medication classes not payable together:
  - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.

### Dual endothelin angiotensin receptor antagonist

| CLINICAL PA REQUIRED |
|---|
| FILSPARI (sparsentan) |

### Factor B Inhibitors

| CLINICAL PA REQUIRED |
|---|
| FABHALTA (iptacopan) |

### Kappa-opioid agonist

| CLINICAL PA REQUIRED |
|---|
| KORSUVA (difelikefalin) – *Medical Billing* |

### Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

| CLINICAL PA REQUIRED |
|---|
| KERENDIA (finerenone) |

### Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

| NO PA REQUIRED |
|---|
| ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred* |

| |
|---|
| ARBs (angiotensin receptor blockers) – *all oral agents preferred* |
| TEKTURNA (aliskiren) |

## SGLT-1/SGLT-2 Inhibitor

| CLINICAL PA REQUIRED |
|---|
| INPEFA (sotagliflozin) |

## SGLT-2 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FARXIGA (dapagliflozin) – *Brand Required* | dapagliflozin |
| JARDIANCE (empagliflozin) | INVOKANA (canagliflozin) |
| | INVOKAMET (canagliflozin/metformin) |
| | INVOKAMET XR (canagliflozin/metformin) |

## Sodium/Hydrogen Exchanger 3 (NHE3)

| CLINICAL PA REQUIRED |
|---|
| XPHOZAH (tenapanor) |

## Systemic Corticosteroids

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| methylprednisolone | TARPEYO (budesonide-targeted release) |
| prednisone | |

## Vasopressin V2-receptor (V2R) Antagonist

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| JYNARQUE (tolvaptan) | |

### *Electronic Duration Verification:*

- Tarpeyo is payable for 9 months every 3 years.
- tolvaptan is payable for 30 days every year.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Inpefa Only:*

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

- Clinical justification must be provided explaining why the member is unable to use a preferred SGLT-2 inhibitor (subject to clinical review)

*Kerendia Only*
- The member must have history of diabetes.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 $m^2$
- The member has one of the following (1 or 2) despite a 3-month trial with an ACE inhibitor or a 6-month trial with an ARB, as evidenced by paid claims or pharmacy printouts:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

*Korsuva Only*
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

*Fabhalta and Filspari Only*
- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - systemic corticosteroid

*Tarpeyo Only*
- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be concurrently be on the following agents at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB or Filspari
  - A SGLT-2 inhibitor

*Tolvaptan Only*
- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR ≥ 25
- The prescriber has provided clinical justification that the member is at high risk of kidney progression such as one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan)
  - An annual eGFR decline of at least 5 mL/min/1.73 m2 in one year
  - An annual eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of five years

- A greater than 5 % increase in total kidney volume per year on at least three repeated measurements (via MRI or CT (computed tomography), each at least 6 months apart

*Xphozah Only*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by the following scores and symptoms:
  - *Fabhalta, Filspari and Tarpeyo Only*: proteinuria <0.5 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: The member has experienced a stabilization in eGFR or one of the following:
    - albuminuria <1 gram/day or reduction of 30% from baseline
    - UACR < 1.5 g/g or reduction of 30% from baseline

**References:**


1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.
2. de Boer, Ian H., et al. “Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO).” *Diabetes care* 45.12 (2022): 3075-3090.


# Anemia

## Hematopoietic, Erythropoiesis Stimulating Agents

*Pharmacy Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ARANESP (darbepoetin alfa) | PROCRIT (epoetin alfa) |
| EPOGEN (epoetin alfa) | RETACRIT (epoetin alfa – epbx) – Labelers 59353 |
| MIRCERA (methoxy polyethylene glycol-epoetin beta) | |
| RETACRIT (epoetin alfa – epbx) – Labeler 00069 | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

## HIF-PHIs (Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors)

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| VAFSEO (vadadustat) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

## Hematopoietic Syndrome of Acute Radiation Syndrome

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| NPLATE (romiplostim) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: treatment plan must be documented in request*

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
  - The member has had a ≥ 2 gray exposure to radiation
  - The member has had exposure to radiation and experiencing one of the following:
    - Gross blood loss
    - > 10% decrease in hemoglobin
    - Platelet count < 50,000/microL
    - Absolute neutrophil count < 1000 cells/microL
    - Absolute lymphocyte count < 1000 cells/microL

## Hyperkalemia (Chronic)

| PREFERRED AGENTS (CLINCIAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LOKELMA (sodium zirconium cyclosilicate) | VELTASSA (patiromer) |
| SPS (sodium polystyrene sulfonate) SUSPENSION+ | |

+ SPS can cause intestinal necrosis which may be fatal. Concomitant use of additional sorbitol is not recommended.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- The requested medication must be prescribed by, or in consult with, a nephrologist or cardiologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products, as evidenced by paid claims or pharmacy printouts:
  - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)

*Non-Preferred Agent Criteria:*

- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

*Renewal Criteria – Approval Duration: 12 months*

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline

**Reference:**

1. Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." *Kidney International* 102.5 (2022): S1-S127.

## Primary Hyperoxaluria Type 1 (PH1)

*RNA interference (RNAi)*

| CLINICAL PA REQUIRED |
|---|
| OXLUMO (lumasiran) – *Medical Billing* |
| RIVFLOZA (nedosiran) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist or geneticist
- The member's diagnosis must be documented by one of the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member has a failed to achieve at least a 30% reduction in urinary oxalate excretion after a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day), as evidenced by paid claims or pharmacy printouts.
- The member has not received a liver transplant
- One of the following must be submitted:
  - Elevated urinary oxalate excretion > 1 mmol/1.73 $m^2$ per day or 90 mg/1.73 $m^2$ per day
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, (subject to clinical review) including one of the following scores and symptoms:
  - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
  - Decrease of 30% from baseline or normalization of urinary oxalate excretion
  - Decreased or normalized urinary oxalate: creatinine ratio relative to normative values for age

## Lupus Nephritis

*First Line Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| cyclophosphamide | |
| mycophenolate | |
| systemic oral corticosteroids | |

*Anti-CD20 Monoclonal Antibodies*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab - see Biosimilar Agents | |

### *B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BENLYSTA (belimumab) – *Medical Billing* | |

### *Calcineurin Inhibitors*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| cyclosporine | LUPKYNIS (voclosporin) |
| tacrolimus | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member has an eGFR > 45
- The member must be using concurrently with mycophenolate and a systemic corticosteroid for 3 months, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- The member has experienced a therapeutic response since starting treatment, as evidenced by one of the following:
  - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 to 0.7 g/day)
  - Improvement of serum creatinine (SCr ≤ 1.4 mg/dl)
  - Chronic steroid use to ≤ 7.5 mg/day

## Overactive Bladder

### *Topical Formulations*

| PREFERRED AGENTS (NO PA REQUIRED) |
|---|
| GELNIQUE (oxybutynin) GEL |
| OXYTROL (oxybutynin) PATCH |

### *Oral Solid Dosage Formulations*

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| MYRBETRIQ (mirabegron) – *Brand Required* | fesoterodine ER | darifenacin ER |
| oxybutynin ER | tolterodine | DETROL (tolterodine) |
| oxybutynin tablet | tolterodine ER | DETROL LA (tolterodine) |
| solifenacin | | DITROPAN XL (oxybutynin) |
| tamsulosin | | dutasteride/tamsulosin |
| trospium | | fesoterodine |
| | | flavoxate |
| | | FLOMAX (tamsulosin) |
| | | GEMTESA (vibegron) |
| | | JALYN (dutasteride/tamsulosin) |
| | | mirabegron ER |
| | | TOVIAZ ER (fesoterodine) |

| | | |
|---|---|---|
| | | trospium ER |
| | | VESICARE (solifenacin) |

### *Therapeutic Duplication*

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Non-selective alpha 1 blockers (doxazosin, prazosin, and terazosin) are not allowed with carvedilol or labetalol
  - Carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity

### *Electronic Diagnosis Verification*

- Oxybutynin 2.5 mg: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Electronic Step Therapy Required*

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 30-day supply of a preferred agent at max dose has been paid within 100 days prior to step 1 agent's date of service.
  - PA Required Criteria: The member must have failed A 30-day trial of a preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must have had a 30-day trial of solifenacin and Myrbetriq, as evidenced by paid claims or pharmacy printouts.

#### *Non-Solid Dosage Form*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| oxybutynin syrup | MYRBETRIQ (mirabegron) SUSPENSION |
| | VESICARE (solifenacin) LS SUSPENSION |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.
- Must meet Non-Solid Dosage Forms criteria

### *Therapeutic Duplication*

- Anticholinergic medications (tolterodine, oxybutynin, trospium, fesoterodine) are not covered with Acetylcholinesterase Inhibitors.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

## Phosphate Binders

*Solid Dosage Form*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcium acetate | AURYXIA (ferric citrate) TABLET |
| sevelamer carbonate tablet | RENAGEL (sevelamer HCl) TABLET |
| | RENVELA (sevelamer carbonate) TABLET |
| | sevelamer HCl |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

*Non-Solid Dosage Form*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| lanthanum chew tab | FOSRENOL (lanthanum) CHEWABLE TABLET |
| sevelamer carbonate powder pack | FOSRENOL (lanthanum) POWDER PACK |
| | RENVELA (sevelamer carbonate) POWDER PACK |
| | VELPHORO (sucroferric oxyhydroxide) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility).*
- The member must have failed a 30-day trial of sevelamer carbonate and lanthanum, as evidenced by paid claims or pharmacy printouts.
- Must meet Preferred Dosage Form criteria
- Must meet Non-Solid Dosage Forms criteria

# Neurology

## Alzheimer's Disease

### Cholinesterase Inhibitors

*Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| donepezil 5 mg, 10 mg tablet | ARICEPT (donepezil) |
| galantamine tablet | donepezil 23 mg tablet |
| galantamine ER | donepezil ODT |
| rivastigmine capsule | RAZADYNE (galantamine) |
| | RAZADYNE ER (galantamine) |

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EXELON (rivastigmine) PATCH – *Brand Required* | ADLARITY (donepezil) PATCH |
| | galantamine oral solution |
| | rivastigmine patch |

## NMDA Receptor Antagonists

*Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Memantine | NAMENDA (memantine) |

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| memantine ER capsule sprinkle | memantine oral solution |
| | NAMENDA XR (memantine) CAPSULE SPRINKLE |

## Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | memantine/donepezil |
| | NAMZARIC (memantine/donepezil) |

### *Therapeutic Duplication*

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine).
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

### *Electronic Diagnosis Verification*

- Memantine: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### *Electronic Age Verification*

- Submit chart notes to verify diagnosis for members less than 30 years old

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
- Memantine ER capsule sprinkle: Must meet Non-Solid Dosage Forms criteria

## Amyloid Beta-Directed Monoclonal Antibody

| CLINICAL PA REQUIRED |
|---|
| KISUNLA (donanemab-azbt) – *Medical Billing* |
| LEQEMBI (lecanemab-irmb) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a neurologist, geriatric psychiatrist, or geriatrician specializing in dementia.
- The member must have been diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain.
- The member has a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

*Renewal Criteria – Approval Duration: 1 year*

- The member continues to show positive clinical response, such as stable or improved cognitive function

## Amyotrophic Lateral Sclerosis (ALS)

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| riluzole tablet | edaravone – *Medical Billing* | RILUTEK (riluzole) TABLET |
| | EXSERVAN (riluzole) FILM | |
| | QALSODY (tofersen) + – *Medical Billing* | |
| | RADICAVA (edaravone) – *Medical Billing* | |
| | RADICAVA ORS (edaravone) | |
| | TIGLUTIK (riluzole) ORAL SUSPENSION | |

+ Qalsody failed to demonstrate statistically significant benefit over placebo on the primary efficacy endpoint, the change from baseline to Week 28 in the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFS-R) in the Phase 3 VALOR trial (NCT02623699 or clinical secondary endpoints. Continued approval of Qalsody for this indication may be contingent upon verification of clinical benefit in the ATLAS study (NCT04856982).

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member has had ALS symptoms present for less than 2 years.
- The member must have both of the following:
  - Forced vital capacity (FVC) > 80 percent of predicted.
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
- The member must not have permanent invasive ventilation.

*Exservan and Tiglutik Only:* Must meet Non-Solid Dosage Forms criteria

*Renewal Criteria – Approval Duration: 12 months*

- The member must have both of the following:
  - Forced Vital Capacity (FVC) > 60 percent of predicted
  - The member has received a therapeutic response (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by a score decline of less than 6 on the ALSFRS-R.

# Anticonvulsants

## Anticonvulsant Prevention

### Narrow Spectrum:

*Carbamazepine*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| carbamazepine 100 mg chewable tablet | carbamazepine 200 mg chewable tablet |
| carbamazepine oral suspension | carbamazepine ER capsule |
| carbamazepine tablet | carbamazepine XR tablet |
| CARBATROL (carbamazepine) – *Brand Required* | EPITOL (carbamazepine) |
| EQUETRO (carbamazepine) | TEGRETOL (carbamazepine oral suspension) |
| TEGRETOL XR (carbamazepine) – *Brand Required* | TEGRETOL (carbamazepine) |

*Ethosuximide*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ethosuximide capsule | ZARONTIN (ethosuximide) |
| ethosuximide oral solution | ZARONTIN (ethosuximide) ORAL SOLUTION |

*Gabapentin*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| gabapentin capsule | NEURONTIN (gabapentin) CAPSULE |
| gabapentin oral solution | NEURONTIN (gabapentin) ORAL SOLUTION |
| gabapentin tablet | NEURONTIN (gabapentin) TABLET |

*Lacosamine*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| lacosamide oral solution | MOTPOLY XR (lacosamide) CAPSULE |
| lacosamide tablet | VIMPAT (lacosamide) ORAL SOLUTION |
| | VIMPAT (lacosamide) TABLET |

*Oxcarbazepine*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| oxcarbazepine oral solution | oxcarbazepine ER |
| oxcarbazepine tablet | OXTELLAR XR (oxcarbazepine) – *Brand Required* |
| | TRILEPTAL (oxcarbazepine) |
| | TRILEPTAL (oxcarbazepine) ORAL SUSPENSION |

*Pregabalin*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pregabalin | LYRICA (pregabalin) |
| pregabalin oral solution | LYRICA (pregabalin) ORAL SOLUTION |
| | LYRICA CR (pregabalin) |
| | pregabalin ER |

*Phenytoin*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| phenytoin chewable tablet | DILANTIN (phenytoin) CHEWABLE TABLET |
| phenytoin sodium ER | DILANTIN (phenytoin) ORAL SUSPENSION |
| phenytoin suspension | DILANTIN ER (phenytoin) |
| | PHENYTEK (phenytoin) |

*Primidone*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| primidone | MYSOLINE (primidone) |

*Tiagabine*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tiagabine | |

*Vigabatrin*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| SABRIL (vigabatrin) TABLET – *Brand Required* | SABRIL (vigabatrin) POWDER PACK |
| vigabatrin powder pack | vigabatrin tablet |
| | VIGADRONE (vigabatrin) |
| | VIGAFYDE (vigabatrin) |
| | VIGPODER (vigabatrin) |

*Other*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| APTIOM (eslicarbazepine) | methsuximide |
| CELONTIN (methsuximide) – *Brand Name Required* | |
| DIACOMIT (stiripentol) | |
| EPIDIOLEX (cannabidiol) | |
| FINTEPLA (fenfluramine) ORAL SOLUTION | |
| phenobarbital elixir | |
| phenobarbital tablet | |
| XCOPRI (cenobamate) | |
| ZTALMY (ganaxolone) SUSPENSION | |

*Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

### *Electronic Concurrent Medications Required*

- A total of 28 days of clobazam must be paid within 45 days prior to Diacomit.
    - Diacomit is FDA approved to be used in combination with clobazam.

### *Quantity Limit Override*

- Gabapentin: 2400 mg max dose per day

  Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 2400 mg per day and the indication is adjuvant seizure (if monotherapy, please send chart notes to verify indication)

### *Prior Authorization Criteria:*

- See Preferred Dosage Form Criteria

### *Therapeutic Duplication*

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

  Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

## Broad Spectrum:

*Clobazam*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Clobazam | ONFI (clobazam) |
| clobazam oral solution | ONFI (clobazam) ORAL SOLUTION |
| | SYMPAZAN (clobazam) FILM |

*Divalproex/Valproic Acid*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| divalproex sodium ER | DEPAKENE (valproic acid) CAPSULE |
| divalproex sodium sprinkle | DEPAKENE (valproic acid) ORAL SOLUTION |
| divalproex sodium tablet | DEPAKOTE SPRINKLE (divalproex sodium) |
| valproic acid capsule | DEPAKOTE (divalproex sodium) TABLET |
| valproic acid oral solution | DEPAKOTE ER (divalproex sodium) |

*Felbamate*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| felbamate oral suspension | felbamate tablet |
| FELBATOL (felbamate) TABLET– *Brand Required* | |

*Lamotrigine*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| lamotrigine chewable tablet | LAMICTAL (lamotrigine) CHEWABLE TABLET |
| lamotrigine ER | LAMICTAL (lamotrigine) DOSE PACK |
| lamotrigine ODT | LAMICTAL (lamotrigine) TABLET |
| lamotrigine ODT dose pack | lamotrigine dose pack |
| lamotrigine tablet | LAMICTAL ODT (lamotrigine) |
| SUBVENITE (lamotrigine) | LAMICTAL ODT (lamotrigine) DOSE PACK |
| | LAMICTAL XR (lamotrigine) |
| | LAMICTAL XR (lamotrigine) DOSE PACK |
| | SUBVENITE (lamotrigine) DOSE PACK |

*Levetiracetam*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| levetiracetam ER | ELEPSIA XR (levetiracetam) |
| levetiracetam oral solution | KEPPRA (levetiracetam) |
| levetiracetam tablet | KEPPRA (levetiracetam) ORAL SOLUTION |
| | KEPPRA XR (levetiracetam) |
| | levetiracetam tablet for suspension |
| | SPRITAM (levetiracetam) TAB FOR SUSPENSION |

*Rufinamide*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rufinamide suspension | BANZEL (rufinamide) TABLET |
| rufinamide tablet | BANZEL (rufinamide) ORAL SUSPENSION |

*Topiramate*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EPRONTIA (topiramate) SOLUTION | TOPAMAX (topiramate) |
| QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Required* | TOPAMAX (topiramate) SPRINKLE CAPSULE |
| topiramate sprinkle capsule 15 mg, 25 mg | topiramate ER sprinkle cap |
| topiramate tablet | topiramate sprinkle capsule 50 mg |
| TROKENDI XR (topiramate) – *Brand Required* | |

*Other*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BRIVIACT (brivaracetam) | |
| FYCOMPA (perampanel) | |
| FYCOMPA (perampanel) ORAL SUSPENSION | |
| Zonisamide | |

## Anticonvulsant Rescue Therapies

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| diazepam pediatric rectal gel | LIBERVANT (diazepam) FILM |
| diazepam rectal gel | |
| NAYZILAM (midazolam) NASAL SPRAY | |

| | |
|---|---|
| VALTOCO (diazepam) NASAL SPRAY | |

*Electronic Duration Verification*

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for a seizure (in this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

*Prior Authorization Criteria:*

- See Preferred Dosage Form criteria

# Duchenne Muscular Dystrophy

## Corticosteroids

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AGAMREE (vamorolone) | deflazacort |
| EMFLAZA (deflazacort) – *Brand Required* | |

*Prior Authorization Criteria*

Prior Authorization Form – Duchenne Muscular Dystrophy

*Initial Criteria – Approval Duration: 6 months*
*(approval may be granted for tapering if all initial criteria are not met)*

- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by echo
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)

        - 4 stair climb (4SC)
- The member must have ONE of the following significant intolerable adverse effects to prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Motor function assessment
        - 6MWT – improvement of 35 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
        - PUL – improvement of 4 points from baseline
        - 4SC – improvement of 1 second from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

**References:**


1. Muntoni, Francesco, et al. "Meaningful changes in motor function in Duchenne muscular dystrophy (DMD): A multi-center study." *PloS one* 19.7 (2024): e0304984.


## Histone Deacetylase Inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DUVYZAT (givinostat) | |

### *Prior Authorization Criteria*

Prior Authorization Form – Duchenne Muscular Dystrophy

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene.
- The member must have a baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Weight and calculated dose must be provided consistent with approved FDA dose.

- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims and pharmacy print outs.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have maintained a 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, subject to clinical review, including:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)

## Genetic Therapies

### *Adeno-Associate Virus Vector*

| CLINICAL PA REQUIRED |
|---|
| ELEVIDYS (delandistrogene moxeparvovec-rokl) – *Medical Billing* |

### *Exon 45 Skipping*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AMONDYS 45 (casimersen) – *Medical Billing* | |

### *Exon 51 Skipping*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EXONDYS 51 (eteplirsen) – *Medical Billing* | |

### *Exon 53 Skipping*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| VILTEPSO (viltolarsen) – *Medical Billing* | VYONDYS 53 (golodirsen) – *Medical Billing* |

**High-Cost Drug:**
Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.
Elevidys is a once-per-lifetime treatment that costs > $3 million.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.

- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.
- Elevidys is awaiting verification of clinical benefit in confirmatory trials. This gene therapy received traditional approval for ambulatory patients aged 4 years and older, and accelerated approval for non-ambulatory patients in the same age group. However, this decision was made despite the drug failing to meet its primary endpoint in a pivotal Phase III clinical trial. Consider also: administering adeno-associated virus (AAV) vector therapy to patients may prevent them from accessing future, potentially more effective gene therapies, as it can lead to the development of neutralizing antibodies against the viral vector.

## *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 8 weeks*

- The member must be assigned male at birth between ages of 4 and 19 years old
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- The member must meet the following parameters:
  - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy, including Elevidys

*Initial Criteria (Elevidys only)*

- The member must be assigned male at birth between the ages of 4 and 7
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The member cannot have any deletion in exon 8 and/or exon 9 in the DMD gene
- The member does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400
- The member must be ambulatory as confirmed by the North Star Ambulatory Assessment (NSAA) scale (score of ≥ 1)
- The member is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen)

## *Non-Preferred Agent Criteria (Initial)*

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

*Renewal Criteria – Approval Duration: 12 months (Elevidys is for one-time use only and will not be renewed)*

- The member must meet the following parameters:
  - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO

## Huntington's Disease

| CLINICAL PA REQUIRED |
|---|
| AUSTEDO (deutetrabenazine) |
| AUSTEDO XR (deutetrabenazine) |
| INGREZZA (valbenazine) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist.
- The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts.

## Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| Armodafinil | SUNOSI (solriamfetol) | NUVIGIL (armodafinil) |
| Modafinil | XYREM (sodium oxybate) *– Brand Required* | PROVIGIL (modafinil) |
| | | sodium oxybate |
| | | WAKIX (pitolisant) |
| | | XYWAV (sodium, calcium, magnesium, potassium oxybate) |

### *Electronic Step Therapy Required*

- Sunosi and Xyrem:
    - PA Not Required Criteria: A 30-day supply of armodafinil or modafinil has been paid within 60 days prior to preferred step 1 agent's date of service.
    - PA Required Criteria: The member must have failed a 30-day trial of armodafinil or modafinil, as evidenced by paid claims or pharmacy printouts.
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:
    - Multiple Sleep Latency Test (MSLT) <8 minutes
    - EPWORTH sleepiness scale score ≥10
- Xywav Only:
    - The member must have failed a 30-day trial with Wakix, as evidenced by paid claims or pharmacy printouts.
    - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).

*Renewal Criteria – Approval Duration: 12 months*

- The member must have received a therapeutic response, as evidenced by one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) < 8 minutes
  - EPWORTH sleepiness scale score ≥10

### *Therapeutic Duplication*

- Sunosi and Wakix are not allowed together.
- Provigil and Nuvigil are not allowed together.
- Xyrem and, Xywav are not allowed with each other, sleeping medication or benzodiazepines.

### *Underutilization*

- Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

# Migraine

## Prophylaxis of Episodic Migraine

### Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| AIMOVIG (erenumab-aooe) | NURTEC ODT (rimegepant) TABLETS | QULIPTA (atogepant) TABLETS |
| AJOVY (fremanezumab-vfrm) | | VYEPTI (eptinezumab-jjmr) – *Medical Billing* |
| EMGALITY (galcanazumab-gnlm) | | |

### *Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 6 months*

- The member must experience 3 or more migraine days per month.
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide
- *Nurtec ODT Only:*
  - The member must have failed a 3-month trial of Ajovy and Emgality, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agents Criteria*:

- *Qulipta Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, Qulipta and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

## Prophylaxis of Chronic Migraine

### Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AIMOVIG (erenumab-aooe) | QULIPTA (atogepant) TABLETS |
| AJOVY (fremanezumab-vfrm) | VYEPTI (eptinezumab-jjmr) – *Medical Billing* |
| EMGALITY (galcanazumab-gnlm) | |

*Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 6 months*

- The member must experience 3 or more migraine days per month.
- The member must have failed a 2-month trial of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide

*Non-Preferred Agents Criteria*:

- *Qulipta Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, and Aimovig, as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Qulipta, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

## Treatment of Migraine

### Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

*Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time.

**Oral**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NURTEC ODT (rimegepant) | UBRELVY (ubrogepant) |

*Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 3 months*
- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agents Criteria:*
- The member must have failed a 30-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

**Nasal**

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ZAVZPRET NASAL SPRAY (zavegepant) |

### *Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 3 months*

*Non-Preferred Agents Criteria:*
- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists), one of which must be nasal route, of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT, Ubrelvy, and Reyvow, as evidenced by paid claims or pharmacy printouts.

## Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NSAIDS | ELYXYB (celecoxib) |

### *Prior Authorization Criteria:*

- See Preferred Dosage Form criteria

## Serotonin (5-HT) 1F Receptor Agonist

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | REYVOW (lasmiditan) |

### *Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 3 months*
- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT and Ubrelvy, as evidenced by paid claims or pharmacy printouts.

### *Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time

## Ergot Alkaloids

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | D.H.E.45 (dihydroergotamine) INJECTION |
| | dihydroergotamine injection |
| | dihydroergotamine nasal spray |
| | ERGOMAR (ergotamine) SL TABLET |
| | MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY |
| | TRUDHESA (dihydroergotamine) |

### *Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 3 months*

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

### *Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time

## Triptans (5HT-1 Agonists)

### *Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED STEP 1 AGENTS (PA REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| RELPAX (eletriptan) – *Brand Required* | FROVA (frovatriptan) TABLET – *Brand Required* | almotriptan tablet |
| rizatriptan tablet | naratriptan tablet | AMERGE (naratriptan) TABLET |
| sumatriptan tablet | zolmitriptan tablet | eletriptan tablet |
| | | frovatriptan tablet |
| | | IMITREX (sumatriptan) TABLET |
| | | MAXALT (rizatriptan) TABLET |
| | | sumatriptan/naproxen tablet |
| | | TREXIMET (sumatriptan/naproxen) TABLET |
| | | ZOMIG (zolmitriptan) TABLET |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Non-Preferred Step 1 Agents:*

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.

- Members over 18 years old: The member must also have failed a 30-day trial of sumatriptan and eletriptan, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Step 2 Agents:*
- The member must have failed a 30-day trial of each available preferred and non-preferred step 1 triptan agent, as evidenced by paid claims or pharmacy printouts

### *Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time

#### *Non-Solid Oral Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rizatriptan ODT | MAXALT MLT (rizatriptan) |
| | zolmitriptan ODT |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must have failed a 30-day trial of rizatriptan ODT, as evidenced by paid claims or pharmacy printouts.

### *Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time

#### *Nasal Spray*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| sumatriptan spray | TOSYMRA (sumatriptan) NASAL SPRAY |
| | ZOMIG (zolmitriptan) NASAL SPRAY |
| | zolmitriptan spray |

#### *Injectable*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| sumatriptan injectable | IMITREX (sumatriptan) INJECTABLE |
| | ZEMBRACE SYMTOUCH (sumatriptan) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must be unable to take oral medications or experience nausea/emesis with oral triptans (subject to clinical review).
- Zolmitriptan Nasal Spray Only:
  - The member must have failed a 30-day trial with sumatriptan nasal spray, as evidenced by paid claims or pharmacy printouts.
- Sumatriptan 4mg Injectable Only:
  - The member must have failed a 30-day trial with each of the following: sumatriptan 6mg injectable and nasal spray, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agent Criteria:*

- See Preferred Dosage Form criteria

*Therapeutic Duplication*

- One strength of one medication for treatment of migraine is allowed at a time

# Cluster Headache

## Cluster Headache Prevention

| CLINICAL PA REQUIRED |
|---|
| EMGALITY (galcanazumab-gnlm) |

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

*Prior Authorization Criteria*

Prior Authorization Form – Migraine Prophylaxis/Treatment

*Initial Criteria – Approval Duration: 3 months*

- The member has had at least five attacks fulfilling criteria A-C
  - *A.* Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - *B.* Occurring with a frequency of at least every other day
  - *C.* The member must have at least one of the following:
    - A sense of restlessness or agitation
    - Any of the following symptoms or signs, ipsilateral to the headache:
      - Conjunctival injection and/or lacrimation
      - Nasal congestion and/or rhinorrhea
      - Eyelid edema
      - Forehead and facial swelling
      - Miosis and/or ptosis
- The member must have had a 2-month trial with verapamil, as evidenced by paid claims or pharmacy printouts.

# Myasthenia Gravis

## Glucocorticoid-Sparing Therapy

*Oral Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Azathioprine | |
| Cyclosporine | |
| mycophenolate mofetil | |
| Tacrolimus | |

*Biologic Agents*

**Acetylcholine Receptor (AChR) Antibody Positive**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| rituximab - see Biosimilar Agents | SOLIRIS (eculizumab) – *Medical Billing* |
| **PREFERRED AGENTS (CLINICAL PA REQUIRED)** | |
| ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing* | |
| RYSTIGGO (rozanolixizumab-noli) – *Medical Billing* | |
| VYVGART (ergartigimod alfa) – *Medical Billing* | |
| VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing* | |
| ZILBRYSQ (zilucoplan) | |

**Muscle Specific Kinase (MuSK) Positive**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab - see Biosimilar Agents | RYSTIGGO (rozanolixizumab-noli) – *Medical Billing* |

## *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months (1 year total for bridge therapy)*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member must have all of the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
  - Positive serological lab test for one of the following (A or B):
    A. Anti-AchR antibodies
    B. Anti-MuSK antibodies
- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6
  - For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
  - For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms)

*Acetylcholine Receptor (AChR) Antibody Positive*

- One of the following (A or B):
  A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus), as evidenced by paid claims or pharmacy printouts.
- Soliris Only:
  - The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following, as evidenced by paid claims or pharmacy printouts:
    A. Rituximab
    B. Ultomiris
    C. Vyvgart or Rystiggo

*Muscle Specific Kinase (MuSK) Positive*

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial of rituximab, as evidenced by paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following scores and symptoms (subject to clinical review):
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score

# Multiple Sclerosis

## Injectable Agents

### *B-cell and T-cell Therapies*

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED AGENTS (PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|---|
| BRIUMVI (ublituximab-xiiy) *– Medical Billing* | TYSABRI (natalizumab) *– Medical Billing* | MAVENCLAD (cladribine) |
| KESIMPTA (ofatumumab) | | LEMTRADA (alemtuzumab) *– Medical Billing* |
| OCREVUS (ocrelizumab) *– Medical Billing* | | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
*Tysabri Only:*
- The requested medication must be prescribed by, or in consult with, a neurologist

*Non-Preferred Agents:*
- The member must have failed a 3-month trial of two agents in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

### *Interferons*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AVONEX (interferon beta-1A) PEN | BETASERON (interferon beta-1B) |
| AVONEX (interferon beta-1A) SYRINGE | EXTAVIA (interferon beta-1B) |
| AVONEX (interferon beta-1A) VIAL | PLEGRIDY (peginterferon beta-1A) PEN |
| | PLEGRIDY (peginterferon beta-1A) SYRINGE |
| | REBIF (interferon beta-1A) |
| | REBIF REBIDOSE (interferon beta-1A) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must have failed a 3-month trial of the preferred agent in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

*Non-Interferons*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| COPAXONE (glatiramer) 20 MG/ML – *Brand Required* | COPAXONE (glatiramer) 40 MG/ML |
| | glatiramer 20 mg/ml |
| | glatiramer 40 mg/ml |
| | GLATOPA (glatiramer) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Copaxone: See Preferred Dosage Form criteria

## Oral Agents

*Fumerates*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dimethyl fumarate | BAFIERTAM (monomethyl fumarate) |
| | TECFIDERA (dimethyl fumarate) |
| | VUMERITY (diroximel fumarate) |

*Pyrimidine Synthesis Inhibitor*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Teriflunomide | AUBAGIO (teriflunomide) |

*Sphingosine 1-Phosphate (S1P) Receptor Modulators*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fingolimod 0.5 mg | GILENYA (fingolimod) 0.5 MG |
| GILENYA (fingolimod) 0.25 MG | MAYZENT (siponimod) |
| TASCENSO ODT (fingolimod) | PONVORY (ponesimod) |
| | ZEPOSIA (ozanimod) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 3-month trial of all oral preferred agents of an unique ingredient, as evidenced by paid claims or pharmacy print outs.

## Neuromyelitis Optica Spectrum Disorder

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ENSPRYNG (satralizumab-mwge) | SOLIRIS (eculizumab) – *Medical Billing* |
| ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing* | |
| UPLIZNA (inebilizumab) – *Medical Billing* | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
- The member has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
- The member has an Expanded Disability Status Score (EDSS) of ≤ 6.5
- The member must have one of the core clinical characteristics from the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

*Non-Preferred Agents Criteria*
- The member must have had a 3-month trial with Enspryng, Ultomiris and Uplizna, as evidenced by paid claims or pharmacy print outs:

*Renewal Criteria – Approval Duration: 12 months*
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, subject to clinical review, including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

## Pseudobulbar Affect (PBA)

| CLINICAL PA REQUIRED |
|---|
| NUEDEXTA (dextromethorphan/quinidine) |

### *Prior Authorization Criteria*

Prior Authorization Form – Nuedexta

*Initial Criteria – Approval Duration: 3 months*
- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block.
- The following must be provided:
  - Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count
- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
  - Amytrophic Lateral Sclerosis (ALS)
  - Multiple Sclerosis (MS)
  - Alzheimer's Disease
  - Stroke
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
  - Neurologic condition must have been stable for at least 3 months
  - Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
    - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
    - Tricyclic Antidepressants: nortriptyline and amitriptyline

- Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
  - PBA count has not decreased by more than 75 percent from baseline
  - CNS-LS score has not decreased by more than 7 points from baseline

*Renewal Criteria – Approval Duration: 6 months*

- Benefit of continued therapy must be assessed.
  - Spontaneous improvement of PBA occurs and should be ruled out periodically before continuing medication.
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
  - Current CNS-LS score must be reduced by at least 30% from baseline
- For all other indications:
  - Current PBA episode must be reduced by at least 75% from baseline

# Parkinson's disease

## Parkinson's Agents – First Line Therapy

### Parkinson's Agents – Levodopa

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| carbidopa-levodopa-entacapone<br>25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg | carbidopa-levodopa-entacapone<br>12.5 mg/50 mg, 18.75 mg/75 mg, 31.25 mg/125 mg |
| carbidopa-levodopa | CREXONT (carbidopa-levodopa ER) |
| carbidopa-levodopa ER | DHIVY (carbidopa-levodopa) |
| carbidopa-levodopa ODT | SINEMET (carbidopa-levodopa) TABLET |
| RYTARY (carbidopa-levodopa) ER CAPSULE | STALEVO (carbidopa-levodopa-entacapone) |

*Prior Authorization Criteria*

- See Preferred Dosage Form criteria

## Parkinson's Agents – Adjunctive Therapy

### Parkinson's Agents – Adenosine Receptor Agonists

*Oral*

| CLINICAL PA REQUIRED |
|---|
| NOURIANZ (Istradefylline) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of "off" time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts..
- The member has had a previous response to levodopa.

*Renewal Criteria – Approval Duration: 12 months*

- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

## Parkinson's Agents - Amantadine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amantadine IR capsule | amantadine IR tablet |
| amantadine solution | GOCOVRI (amantadine ER) |
| | OSMOLEX ER (amantadine ER) |

### *Electronic Age Verification:*

- Amantadine: Member must be 18 years old or older

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must not reside in facility where medications are managed such as skilled nursing care.
- See Preferred Dosage Form Criteria

## Parkinson's Agents – Anticholinergics

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| benztropine | COGENTIN (benztropine) |
| trihexyphenidyl | |

## Parkinson's Agents – COMT inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| entacapone | COMTAN (entacapone) |
| TASMAR (tolcapone) – *Brand Required* | ONGENTYS (opicapone) |
| | Tolcapone |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

## Parkinson's Agents – Ergot Dopamine Receptor Agonists

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Bromocriptine | PARLODEL (bromocriptine) |

## Parkinson's Agents – MAO-B Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| Rasagiline | AZILECT (rasagiline) |
| selegiline | EMSAM (selegiline) PATCH |
| ZALAPAR ODT (selegiline) | XADAGO (safinamide) |

### *Prior Authorization Criteria*

Emsam Only:
- See *Preferred Dosage Form* and Non-Solid Oral Dosage Form criteria

Xadago Only:
- *Initial Criteria – Approval Duration: 3 months*
    - The requested medication must be prescribed by, or in consult with, a neurologist
    - The member has a minimum of 3 hours of "off" time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
    - The member has had a previous response to levodopa.

- *Renewal Criteria – Approval Duration: 12 months*
    - The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

## Parkinson's Agents – Non-ergot Dopamine Receptor Agonists

### *Oral*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pramipexole IR | MIRAPEX (pramipexole) |
| ropinirole IR | MIRAPEX ER (pramipexole) |
| ropinirole ER | pramipexole ER |
| | REQUIP (ropinirole) |

### *Topical*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | NEUPRO (rotigotine) PATCH |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Pramipexole ER: See Preferred Dosage Form criteria

## Parkinson' Agents – Device-Assisted Refractory Therapies

### *Enteral Suspension*

| CLINICAL PA REQUIRED |
|---|
| DUOPA (levodopa/carbidopa) |

### *Subcutaneous*

| CLINICAL PA REQUIRED |
|---|
| VYALEV (foscarbidopa/foslevodopa) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 3 months*

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of "off" time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
- The member has had a previous response to levodopa.

*Renewal Criteria – Approval Duration: 12 months*

- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

## Parkinson's Agents – On-Demand Rescue for "Off" Episodes

### *Subcutaneous*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| APOKYN (apomorphine) – *Brand Required* | apomorphine |

### *Inhalation*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| INBRIJA (levodopa) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- The number and frequency of intermittent hypomobility or off episodes must be provided.
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response
  - The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

# Spinal Muscular Atrophy (SMA)

## SMN2 Gene Splicing Modifiers

| CLINICAL PA REQUIRED |
|---|
| EVRYSDI (risdiplam) |
| SPINRAZA (nusinersen) – *Medical Billing* |

### *Prior Authorization Criteria*

Prior Authorization Form – Evrysdi

*Initial Criteria – Approval Duration: 12 months*

- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following:

- Bi-allelic deletions or mutations of SMN1 as confirmed by genetic testing, reported as one of the following:
  - Homozygous deletions of exon 7
  - Compound heterozygous mutations
- One of the following:
  - The member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
  - The member is symptomatic (e.g., loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)

- The requested medication must be prescribed by, or in consult with, a neuromuscular neurologist or neuromuscular physiatrist (medical geneticist may be allowed for initial request)
- The member must visit with a neuromuscular clinic - clinic name and contact information and date of last visit must be provided, and date of last visit must be within the last year (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
- The member must not require continuous intubation > 3 weeks
- The member must not have received gene therapy (i.e., Zolgensma)
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member's baseline motor milestone score results must be provided from at least two of the following assessments (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  - Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Motor Function Measure – 32 items (MFM-32)
  - Revised Upper Limb Module (RULM)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC and FEV1) via Pulmonary Function Test

*Renewal Criteria – Approval Duration: 12 months*

- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member must visit with a neuromuscular clinic - clinic name, contact information, and date of last visit must be provided, and date of last visit must be within the last year
- The provider must submit motor milestone score results showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by one of the following:
  - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

## Gene Therapy

| CLINICAL PA REQUIRED |
| --- |
| ZOLGENSMA (onasemnogene abeparvovec) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)*

- The member is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
- The medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1 x $10^{14}$ vector genomes per kilogram)

- Baseline confirmation must be submitted of anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- The member must not have advanced SMA evidenced by one of the following
  - Complete paralysis of limbs
  - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 of more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

## Tardive Dyskinesia

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AUSTEDO (deutetrabenazine) | tetrabenazine 25 mg |
| AUSTEDO XR (deutetrabenazine) | XENAZINE (tetrabenazine) |
| INGREZZA (valbenazine) | |
| tetrabenazine 12.5 mg | |

### *Electronic Step Therapy Required*

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

### *Prior Authorization Criteria*

Prior Authorization Form – Tardive Dyskinesia

*Initial Criteria – Approval Duration: 12 months*
- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist. The member must have a history of treatment with a dopamine receptor blocking agent (DRBA) or dopamine receptor modifier that reduces dopaminergic tone (i.e., a partial agonist).
- The member must have a total AIMS score (items 1-7) of ≥ 6 or AIMS score on item 8 or item 9 ≥ 3

*Renewal Criteria – Approval Duration: 12 months*
- The member must have had improvement in AIMS score from baseline

# Obstetrics/Gynecology

## Endometriosis Pain

| CLINICAL PA REQUIRED |
|---|
| MYFEMBREE (relugolix, estradiol, and norethindrone acetate) |
| ORILISSA (elagolix) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*
- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

*Renewal Criteria – Approval Duration: 18 months*

- The member must have received therapeutic response, as evidenced by improvement in pain score from baseline

*Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

## Estrogens

*Injectable*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DELESTROGEN (estradiol valerate) INJECTION – Brand Required | estradiol valerate injection |
| DEPO-ESTRADIOL (estradiol cypionate) INJECTION | PREMARIN (estrogens, conjugated) INJECTION |

*Oral*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| estradiol tablet | ACTIVELLA (estradiol-norethindrone) TABLET |
| estradiol-norethindrone tablet | AMABELZ (estradiol-norethindrone) TABLET |
| norethindrone-ethinyl estradiol tablet | BIJUVA (estradiol-progesterone) CAPSULE |
| PREMARIN (estrogens, conjugated) TABLET | ESTRACE (estradiol) TABLET |
| PREMPHASE (estrogen, conj. M-progest) TABLET | FEMHRT (norethindrone-ethyl estradiol) TABLET |
| PREMPRO (estrogen, conj. M-progest) TABLET | FYAVOLV (norethindrone-ethinyl estradiol) TABLET |
| | MENEST (estrogens, esterified) TABLET |
| | JINTELI (norethindrone-ethinyl estradiol) TABLET |
| | MIMVEY (estradiol-norgestimate) TABLET |
| | PREFEST (estradiol-norgestimate) TABLET |

*Topical Gel/Spray*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ELESTRIN (estradiol) GEL MDP | DIVIGEL (estradiol) GEL PACKET |
| EVAMIST (estradiol) SPRAY | estradiol gel |

*Topical Patch*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALORA (estradiol) PATCH TWICE WEEKLY *- Brand Required* | CLIMARA (estradiol) PATCH WEEKLY |
| CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY | DOTTI (estradiol) PATCH TWICE WEEKLY |
| COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY | estradiol patch twice weekly |
| estradiol patch weekly | LYLLANA (estradiol) PATCH TWICE WEEKLY |
| MENOSTAR (estradiol) PATCH ONCE WEEKLY | |
| MINIVELLE (estradiol) PATCH TWICE WEEKLY *- Brand Required* | |
| VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY *- Brand Required* | |

*Vaginal*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| estradiol vaginal cream | ESTRACE (estradiol) CREAM |
| ESTRING (estradiol) | estradiol vaginal tablet |
| FEMRING (estradiol) | YUVAFEM (estradiol) VAGINAL TABLET |
| PREMARIN (estrogens, conjugated) CREAM | |
| VAGIFEM (estradiol) VAGINAL TABLET<br>*– Brand Required* | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

## Long-Acting Contraception

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time

## Menopause – Vasomotor Symptoms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| citalopram | BRISDELLE (paroxetine mesylate) |
| clonidine | paroxetine mesylate 7.5mg capsules |
| desvenlafaxine | VEOZAH (fezolinetant) |
| escitalopram | |
| estrogen products | |
| gabapentin | |
| oxybutynin | |
| paroxetine hydrochloride tablets | |
| venlafaxine | |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months*

- BOTH of the following must be met (1 and 2):
  1. One of the following must be met (a or b):
     a. The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
     b. The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
  2. The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:

    - SNRI: Venlafaxine or desvenlafaxine
    - SSRI: citalopram, escitalopram, or paroxetine
- Paroxetine mesylate: See Preferred Dosage Form Criteria

**References:**


1. Khan SJ, Kapoor E, Faubion SS, Kling JM. Vasomotor Symptoms During Menopause: A Practical Guide on Current Treatments and Future Perspectives. Int J Womens Health. 2023 Feb 14;15:273-287. doi: 10.2147/IJWH.S365808. PMID: 36820056; PMCID: PMC9938702.


## Mifepristone

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Form – Mifepristone

*Initial Criteria – Approval Duration: 1 month*

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - **A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
    - I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.
    - II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.
  - **B. Both of the following must be met (I and II)**
    - I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed
    - II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

## Nausea/Vomiting – Pregnancy

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DICLEGIS (doxylamine/vitamin B6) – *Brand Required* | BONJESTA (doxylamine/vitamin B6) |
| meclizine | doxylamine/vitamin B6 |
| metoclopramide | |
| ondansetron | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: until due date*

- Member's due date must be provided
- See Preferred Dosage Form criteria

## Progesterone

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| progesterone capsule | |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

# Uterine Fibroids

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| MYFEMBREE (relugolix, estradiol, and norethindrone acetate) | ORIAHNN (elagolix, estradiol, and norethindrone acetate) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

*Renewal Criteria – Approval Duration: 18 months*

- The member has received therapeutic response as evidenced by improvement in pain score from baseline

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

# Vaginal Infections

## Bacterial Infections

### *Oral*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| metronidazole tablet | metronidazole 125 mg tablet |

### *Vaginal*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CLEOCIN (clindamycin) SUPPOSITORY | CLINDESSE (clindamycin) CREAM |
| clindamycin cream | VANDAZOLE (metronidazole) GEL |
| metronidazole gel | |
| NUVESSA (metronidazole) GEL | |
| XACIATO (clindamycin phosphate) GEL | |

## Fungal Infections

*Oral*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fluconazole tablet | BREXAFEMME (ibrexafungerp) TABLETS |
| tinidazole tablet | VIVJOA (oteseconazole) CAPSULES |

*Vaginal*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| terconazole cream | GYNAZOLE 1 (butoconazole) CREAM |
| terconazole suppository – labeler 00713 | terconazole suppository – labeler 45802 |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed 30-day trials of all preferred agents of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- Vivjoa Only:
  - The member must have failed a six-month trial of oral fluconazole maintenance prophylaxis treatment, as evidenced by paid claims or pharmacy printouts.
  - The member must not be of reproductive potential defined as:
    - The member is postmenopausal
    - The member is known to not be of reproductive potential (e.g., history of tubal ligation, salpingo-oophorectomy, or hysterectomy)

# Ophthalmology

## Antihistamines

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| azelastine | ALOMIDE (lodoxamide) |
| BEPREVE (bepotastine) – *Brand Required* | bepotastine |
| cromolyn | epinastine |
| olopatadine 0.1% | olopatadine 0.2% |
| | ZERVIATE (cetirizine) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed 30-day trials of olopatadine and bepotastine, as evidenced by paid claims or pharmacy printouts.

## Anti-infectives

*Drops*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BESIVANCE (besifloxacin) DROPS | AZASITE (azithromycin) DROPS |

| | |
|---|---|
| ciprofloxacin drops | gatifloxacin drops |
| gentamicin sulfate drops | OCUFLOX (ofloxacin) DROPS |
| moxifloxacin drops (generic Vigamox) | VIGAMOX (moxifloxacin) DROPS |
| NATACYN (natamycin) DROPS | |
| neomycin SU/polymyxin B/gramicidin drops | |
| ofloxacin drops | |
| polymyxin B/trimethoprim drops | |
| sulfacetamide drops | |
| tobramycin drops | |

*Ointment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| bacitracin/polymyxin B ointment | bacitracin ointment |
| CILOXAN (ciprofloxacin) OINTMENT | NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT |
| erythromycin ointment | POLYCIN (bacitracin/polymyxin B) OINTMENT |
| neomycin SU/bacitracin/polymyxin B ointment | sulfacetamide ointment |
| TOBREX (tobramycin) OINTMENT | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

## Anti-infectives/Anti-inflammatories

*Drops*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| neomycin/polymyxin b/dexamethasone drops | MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS |
| sulfacetamide/prednisolone drops | neomycin/polymyxin b/hydrocortisone drops |
| tobramycin/dexamethasone drops | |
| TOBRADEX ST (tobramycin/dexamethasone) DROPS | |
| ZYLET (tobramycin/lotepred etab) DROPS | |

*Ointment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| neomycin/polymyxin b/dexamethasone ointment | BLEPHAMIDE (sulfacetamide/prednisone) |
| TOBRADEX (tobramycin/dexamethasone) OINTMENT | MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT |
| | neomycin/bacitracin/polymyxin b/hydrocortisone ointment |
| | NEO-POLYCIN HC (neomycin SU/bacitracin/ polymyxin B/hydrocortisone) OINTMENT |
| | PRED G S.O.P. (gentamicin/prednisone) OINTMENT |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

# Anti-inflammatories

## Corticosteroids

*Drops*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALREX (loteprednol) DROPS – *Brand Required* | clobetasol 0.05% drops |
| DUREZOL (difluprednate) DROPS – *Brand Required* | dexamethasone sodium phosphate drops |
| FLAREX (fluorometholone) DROPS | difluprednate drops |
| fluorometholone drops | INVELTYS (loteprednol) DROPS |
| FML FORTE (fluorometholone) DROPS | fluorometholone drops (labeler 60219) |
| LOTEMAX (loteprednol) DROPS – *Brand Required* | FML LIQUIFILM (fluorometholone) DROPS |
| LOTEMAX (loteprednol) GEL DROPS – *Brand Required* | LOTEMAX SM (loteprednol) DROPS |
| MAXIDEX (dexamethasone) DROPS | loteprednol eye drops |
| PRED MILD 0.12% (prednisolone acetate) DROPS | loteprednol gel eye drops |
| prednisolone acetate 1% drops | PRED FORTE 1% (prednisolone acetate) DROPS |
| prednisolone sodium phosphate 1% drops | |

*Ointment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LOTEMAX (loteprednol) OINTMENT | |

## Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

*Drops*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| diclofenac sodium drops | ACULAR (ketorolac) DROPS |
| ketorolac 0.5% drops | ACULAR LS (ketorolac) DROPS |
| NEVANAC (nepafenac) DROPS | ACUVAIL (ketorolac) DROPS |
| PROLENSA (bromfenac) DROPS – *Brand Required* | bromfenac sodium drops |
| | BROMSITE (bromfenac sodium) DROPS |
| | ILEVRO (nepafenac) DROPS |
| | ketorolac 0.4% drops |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 5-day trial of each preferred agent in the respective therapeutic class, as evidenced by paid claims or pharmacy printouts.

# Dry Eye Syndrome

*Initial Management - Lubricants*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ARTIFICIAL TEARS (dextran/hypromellose/glycerin) | FRESHKOTE (polyvinyl alcohol/povidone) |
| ARTIFICIAL TEARS (polyvinyl alcohol/povidone) | SENTIA (propylene glycol) |
| BION TEARS EYE DROPS (dextran 70/hypromellose) | VENTIVA (propylene glycol) |
| carboxymethylcellulose | VENTIVA (carboxymethylcellulose) |
| DRY EYE RELIEF (peg 400/Hypromellose/glycerin) | |
| GENTEAL TEARS (dextran/hypromellose/glycerin) | |
| GENTEAL TEARS (dextran 70/hypromellose) | |
| GENTEAL TEARS (hypromellose) | |
| LUBRICANT EYE DROPS (carboxymethylcellulose) | |
| LUBRICANT EYE DROPS (propylene glycol/peg 400) | |
| REFRESH (carboxymethylcellulose) | |
| REFRESH (polyvinyl alcohol/povidone) | |
| REFRESH (carboxymethylcellulose/glycerin) | |
| REFRESH (carboxymethylcellulose/glycerin/poly80) | |
| SYSTANE (hypromellose) | |
| SYSTANE (propylene glycol) | |
| SYSTANE (propylene glycol/peg 400) | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

*Persistent Symptoms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED STEP 1 AGENTS (PA REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| EYSUVIS (loteprednol) DROPS | TYRVAYA (varenicline) NASAL SPRAY | CEQUA (cyclosporine) |
| RESTASIS (cyclosporine) DROPPERETTE – *Brand Required* | | cyclosporine dropperette |
| XIIDRA (lifitegrast) | | MIEBO (perfluorohexyloctane) |
| | | RESTASIS MULTIDOSE (cyclosporine) |
| | | VEVYE 0.1% EYE DROP (cyclosporine) |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Non-Preferred Step 1 Agents*

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.

- The member must have failed a 1-month trial of Eysuvis, a 6-month trial of Restasis and a 2-month trial of Xiidra, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Step 2 Agents:*
- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis and a 2-month trial of Xiidra, and a 1-month trial of Eysuvis and Tyrvaya as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria

# Glaucoma

## Alpha Adrenergic

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ALPHAGAN P 0.1% (brimonidine) DROPS – *Brand Required* | apraclonidine 0.5% drops |
| ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required* | brimonidine 0.1% drops |
| brimonidine 0.2% drops | brimonidine 0.15% drops |
| COMBIGAN (brimonidine-timolol) DROPS – *Brand Required* | brimonidine-timolol 0.2%-0.5% drops |
| SIMBRINZA (brinzolamide/brimonidine) DROPS | IOPIDINE (apraclonidine) 1% DROPS |

## Beta Blockers

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BETIMOL (timolol) DROPS | betaxolol 0.5% drops |
| BETOPTIC S (betaxolol) 0.25% DROPS | brimonidine/timolol drops |
| carteolol drops | COSOPT (dorzolamide/timolol) DROPS |
| COMBIGAN (brimonidine/timolol) DROPS – *Brand Name Required* | timolol drops once daily |
| dorzolamide/timolol drops | timolol drops (Betimol generic) |
| ISTALOL (timolol maleate) DROPS ONCE DAILY – *Brand Required* | timolol gel forming solution |
| levobunolol drops | TIMOPTIC (timolol maleate) DROPS |
| timolol maleate drops (Timoptic generic) | TIMOPTIC OCUDOSE (timolol) PF DROPS |
| timolol maleate/PF drops | TIMOPTIC-XE (timolol gel forming solution) |

### *Prior Authorization Criteria*

- See Preferred Dosage Form criteria

## Carbonic Anhydrase Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AZOPT (brinzolamide) – *Brand Required* | brinzolamide |
| dorzolamide | COSOPT (dorzolamide/timolol) |
| dorzolamide/timolol | |
| SIMBRINZA (brinzolamide/brimonidine) | |

## Prostaglandins

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| latanoprost | bimatoprost 0.03% |
| LUMIGAN (bimatoprost) 0.01% | IYUZEH (latanoprost/pf) |
| ROCKLATAN (netarsudil/latanoprost) | tafluprost/pf |
| | TRAVATAN Z (travoprost) |
| | travoprost |
| | VYZULTA (latanoprostene) |
| | XALATAN (latanoprost) |
| | XELPROS (latanoprost) |
| | ZIOPTAN (tafluprost/pf) |

### *Prior Authorization Criteria*

- The member must have failed a 14-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

## Rho Kinase Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| RHOPRESSA (netarsudil) | |
| ROCKLATAN (netarsudil/latanoprost) | |

# Presbyopia

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pilocarpine | ISOPTO CARPINE (pilocarpine) |
| | VUITY (pilocarpine hydrochloride) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- See Preferred Dosage Form criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Clinical justification must be provided (subject to clinical review), including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

*Renewal Criteria – Approval Duration: 12 months*

- Clinical justification must be provided (subject to clinical review), including activities of daily living are positively impacted by drug therapy.

# Inherited Retinal Dystrophy

| CLINICAL PA REQUIRED |
|---|
| LUXTURNA (alglucosidase alfa) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: Approval Duration: 1 month (once per lifetime per eye)*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

## Uveitis

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | |

### *Vernal Keratoconjunctivitis*

| CLINICAL PA REQUIRED |
|---|
| VERKAZIA (cyclosporine) 0.1% |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed* a 3-month trial of combination of each of the following, as evidenced by paid claims or pharmacy printouts:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

*Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

## Ophthalmology Injection- Complement Inhibitors

| CLINICAL PA REQUIRED |
|---|
| IZERVAY (avacincaptad pegol) – *Medical Billing* |
| SYFOVRE (pegcetacoplan) – *Medical Billing* |

Izervay was tested in two key studies (GATHER1 NCT02686658 and GATHER2 NCT04435366) and showed significant reduction in autofluorescence loss at 12 months. However, patients in the treatment groups did not show any improvement in best-corrected visual acuity or low luminance visual acuity compared to placebo.

In two Phase 3 clinical studies of Syfovre (OAKS NCT03525613 and DERBY NCT03525600), at 24 months both studies showed a significant reduction in autofluorescence-detected atrophy compared to placebo. However, there were no functional improvements in visual acuity, reading speed, reading independence, or mean microperimetry sensitivity between the treatment and placebo groups.

### *Prior Authorization Criteria*

For Izervay:
*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥50 years of age
- The member must have a diagnosis of GA not affecting the foveal center point, secondary to AMD
- The member must meet the following requirements:
  - Best-Corrected Visual Acuity (BCVA) between 20/25 and 20/320 in study eye
  - GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2
  - Absence of Choroidal neovascularization (CNV) in both eyes

For Syfovre:
*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥60 years of age
- The member must meet the following requirements:
  - Best-Corrected Visual Acuity (BCVA) ≥ 24 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters
  - GA lesion size ≥2.5 and ≤17.5 mm2 with at least 1 lesion ≥1.25 mm2
  - Presence of extrafoveal lesions
  - Absence of Choroidal neovascularization (CNV) in both eyes

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review

## Ophthalmology Injection- VEGF Inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BEOVU (brolucizumab-dbll) – *Medical Billing* | ranibizumab – See Biosimilar Agents |
| CIMERLI (ranibizumab-eqrn) – *Medical Billing* | SUSVIMO (ranibizumab) – *Medical Billing* |
| EYLEA (aflibercept) – *Medical Billing* | |
| PAVBLU (aflibercept-ayyh) – *Medical Billing* | |

| | |
|---|---|
| VABYSMO (faricimab-svoa) – *Medical Billing* | |

**For the indication:**

1. Retinopathy of prematurity

*Prior Authorization Criteria*

- See Medications that cost over $3000/month criteria

**For the indications:**

1. diabetic macular edema
2. macular edema following central retinal vein occlusion
3. macular edema following branch retinal vein occlusion
4. neovascular (wet) age-related macular degeneration

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must have a mean visual acuity letter score (VALS) of 70 or Best Corrected Visual Acuity of 20/40 or worse at baseline
- The member must have failed a trial consisting of at least 2 doses of a bevacizumab agent, as evidenced by paid claims or pharmacy printouts.
- For Susvimo only: the member must have previously responded to at least two intravitreal injections of a VEGF inhibitor medication (indicated only for neovascular (wet) age-related macular degeneration)

*Renewal Criteria – Approval Duration: 12 months*

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement or stabilization in VALS, defined as a loss of not more than 5 letters compared to baseline.
- The member must have at least a mean VALS of 20 or BCVA of 20/400

# Otic

## Anti-infectives/Anti-inflammatories – Fluoroquinolones

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CIPRO HC (ciprofloxacin/hydrocortisone) | ciprofloxacin/dexamethasone otic drops++ |
| | ciprofloxacin/fluocinolone |

++ Please note, for otitis externa with non-intact tympanic membrane, ciprofloxacin (eye drops) and ofloxacin (eye and ear drops) are required preferred agents.

If all the following conditions apply, please request an override for ciprofloxacin/dexamethasone by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

- The member has tympanostomy tubes
- The member has otitis media
- There is granulation tissue present

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet one of the following:
  - The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

# Pain

## Lidocaine Patch

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| lidocaine 5% patch | LIDODERM (lidocaine) 5% PATCH |
| **PREFERRED AGENTS (PA REQUIRED)** | |
| ZTLIDO (lidocaine) 1.8% PATCH | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of lidocaine 5% patch, as evidenced by paid claims or pharmacy printouts.

## Lidocaine Topical Cream

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The request must be for injection pain from a medically necessary procedure

## NSAIDS

### Oral Solid Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| celecoxib | ARTHROTEC (diclofenac/misoprostol) |
| diclofenac potassium 50 mg tablet | CELEBREX (celecoxib) |
| diclofenac sodium DR 50 mg, 75 mg | DAYPRO (oxaprozin) |
| etodolac | diclofenac potassium 25 mg tablet |
| flurbiprofen | diclofenac potassium 25 mg capsule |
| ibuprofen | diclofenac sodium 25 mg DR |
| indomethacin | diclofenac sodium 100 mg ER tablet |
| indomethacin ER | diclofenac/misoprostol |
| ketoprofen IR | DUEXIS (famotidine/ibuprofen) |
| ketorolac | etodolac ER |
| meclofenamate | famotidine/ibuprofen |
| mefenamic acid | FELDENE (piroxicam) |
| meloxicam | fenoprofen |
| nabumetone | ketoprofen ER 200 mg |
| naproxen | LOFENA (diclofenac potassium) |

| | |
|---|---|
| piroxicam | meloxicam, submicronized |
| sulindac | NALFON (fenoprofen) |
| tolmetin | NAPRELAN (naproxen) |
| VIMOVO (naproxen/esomeprazole) – *Brand Required* | naproxen ER 500 mg |
| | naproxen/esomeprazole |
| | oxaprozin |
| | RELAFEN DS (nabumetone) |
| | SEGLENTIS (celecoxib/tramadol) |

### *Electronic Diagnosis Verification*

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- *Non-preferred agents with same active ingredient preferred*:
  - See Preferred Dosage Form Criteria

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- The member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

## Oral Non-Solid Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ibuprofen suspension | indomethacin solution |
| naproxen suspension | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

## Nasal Dosage Forms

| CLINICAL PA REQUIRED |
|---|
| ketorolac nasal spray |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

## Topical Dosage Forms

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| diclofenac gel | diclofenac 1.3% patch |
| diclofenac topical solution (all other labelers) | diclofenac 2% pump |
| | diclofenac topical solution (labeler 59088) |

### *Prior Authorization Criteria*

- See Preferred Dosage Form Criteria

# Opioid Analgesics

The Centers for Disease Control (CDC) have published guidelines for the prescribing of opioids for pain.

### *Therapeutic Duplication*

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Carisoprodol: The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Methadone is not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Morphine is not covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine (does not include other opioid analgesics)
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).
- Tramadol immediate release with tramadol extended release

### *Opioids and Benzodiazepine Concurrent Use*

Opioid and Benzodiazepines Concurrent Use Form

- Due to guidance in The SUPPORT for Members and Communities Act (H.R. 6) on CNS depression, this includes long-acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose in combination with benzodiazepines.

*Initial Criteria – Approval Duration: 12 months*

- The member has access to an opioid reversal medication and has been counseled on overdose risk.
- The member has been counseled on the risks of utilizing opioids and benzodiazepines in combination with each other and other CNS depressing medications, including antipsychotics and sedatives.
- The member must currently be on long-acting opioid therapy or must not have achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.)
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.

- The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a treatment plan including goals for pain and function, and urine and/or blood screens if the cumulative daily dose of opioids exceeds 90 MME/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).
- The prescriber(s) of both agents have provided reasons why opioid analgesics and benzodiazepines cannot be avoided, or lower doses be used (subject to clinical review).
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.

*Greater than 90 Morphine Milligram Equivalents (MME) per Day:*

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization: an MME calculator may be found at https://www.mdcalc.com/calc/10170/morphine-milligram-equivalents-mme-calculator

*Initial Criteria – Approval Duration: 12 months*

- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a pain management contract with a treatment plan including goals for pain and function, and urine and/or blood screens

# Opioid Analgesics – Long Acting

## Partial Agonist/Antagonist Opioids

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BELBUCA (buprenorphine) | buprenorphine patches |
| Butorphanol | |
| BUTRANS (buprenorphine) PATCHES<br>- *Brand Required* | |

## Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| OXYCONTIN (oxycodone) – *Brand Required* | CONZIP (tramadol ER) CAPSULES |
| tramadol ER Tablets | hydrocodone ER tablets |
| | HYSINGLA ER (hydrocodone) |
| | levorphanol |
| | methadone |
| | MORPHABOND ER (morphine) |
| | tramadol ER capsules |

## Full Agonist Opioids Without Abuse Deterrent Formulations

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr,<br>75 mcg/hr, 100 mcg/hr | fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr |
| morphine ER tablets | hydrocodone ER capsules |
| | hydromorphone ER tablets |
| | morphine ER capsules |

| | |
|---|---|
| | MS CONTIN (morphine) |
| | oxycodone ER |
| | oxymorphone ER tablets |

## *Prior Authorization Criteria*

Prior Authorization Form – Opioid Analgesics

*Initial Criteria – Approval Duration: 12 months*

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to an opioid reversal medication and has been counseled on overdose risk.
  - The member resides in a facility with skilled nursing care.
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy.
  - The member must have been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
  - Both of the following are met:
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
    - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan
  - The member must have with treatment plan including goals for pain and function, and urine and/or blood screens.

*Fentanyl Patch:*

- The member must have a BMI ≥17.

*Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

*Renewal Criteria – Approval Duration: 12 months*

- One of the following must be met:
  - Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
  - The member must be stable on long-acting opioid medication for 2 years or longer.

## *Underutilization*

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

## Opioid Analgesic – Short Acting

*Fentanyl Products*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| fentanyl citrate effervescent tablet | ACTIQ (fentanyl) LOZENGE |
| fentanyl lozenge | FENTORA (fentanyl) EFFERVESCENT TABLET |

*Opioid Combination Solid Oral Products*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| acetaminophen-codeine tablets | ENDOCET (oxycodone-acetaminophen) |
| benzhydrocodone-acetaminophen | hydrocodone-acetaminophen 2.5-325 MG |
| hydrocodone-acetaminophen 5-325 MG | hydrocodone-acetaminophen 10-300 MG |
| hydrocodone-acetaminophen 7.5-325 MG | hydrocodone-acetaminophen 5-300 MG |
| hydrocodone-acetaminophen 10-325 MG | hydrocodone-acetaminophen 7.5-300 MG |
| oxycodone-acetaminophen 5-325 MG, 7.5-325 MG, 10-325 MG | hydrocodone-ibuprofen 5-200 MG and 10-200 MG |
| tramadol-acetaminophen tablets | LORCET (hydrocodone-acetaminophen) |
| hydrocodone-ibuprofen 7.5-200 MG | NALOCET (oxycodone-acetaminophen) |
| | NORCO (hydrocodone-acetaminophen) |
| | oxycodone-acetaminophen 2.5-325 MG |
| | PERCOCET (oxycodone/acetaminophen) |
| | PRIMLEV (oxycodone/acetaminophen) |
| | PROLATE (oxycodone/acetaminophen) |
| | SEGLENTIS (celecoxib/tramadol) |
| | ULTRACET (tramadol/acetaminophen) |
| | VICODIN (hydrocodone/acetaminophen) |

*Opioid – Acetaminophen Combination Non-Solid Oral Products*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| acetaminophen-codeine solution | hydrocodone-acetaminophen 5-163 mg/7.5 mL solution |
| hydrocodone-acetaminophen 7.5-325/15 ml solution | hydrocodone-acetaminophen 10-325/15 ml solution |
| | LORTAB (hydrocodone-acetaminophen) SOLUTION |

*Opioid Single Agent Solid Oral Products*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| codeine tablets | butalbital-codeine tablet |
| hydromorphone tablet | DEMEROL (meperidine) TABLET |
| meperidine tablet | DILAUDID (hydromorphone) TABLET |
| morphine tablet | OXAYDO (oxycodone) TABLET |
| oxycodone 5 mg, 10 mg tablet | oxycodone tablet (Roxybond generic) |
| oxymorphone tablet | oxycodone 15 mg, 20 mg, 30 mg tablet |
| tramadol 50 mg tablet | ROXICODONE (oxycodone) TABLET |
| | ROXYBOND (oxycodone) TABLET |
| | tramadol 25 mg, 75 mg, 100 mg tablet |
| | ULTRAM (tramadol) TABLET |

*Opioid Single Agent Non-Solid Oral Products*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| hydromorphone liquid | |
| morphine solution | |
| oxycodone solution | |

## *First Fill*

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

## *Prior Authorization Criteria*

Prior Authorization Form – Opioid Analgesics

*Initial Criteria – Approval Duration: 12 months*
*Fentanyl Only:*
- The member must currently be on around-the-clock opioid therapy of at least 60 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts

*Meperidine and Butalbital-Codeine Only:*
- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

*Oxycodone IR Only*
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Milligram Equivalent (MME) which meets requirements below (based on requested strength), as evidenced by paid claims or pharmacy printouts (Please use an Opioid Dose Calculator to find the MME for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid must provide ≥150 mg MME per day
  - Oxycodone 20 mg tablet: long-acting opioid must provide ≥200 mg MME per day
  - Oxycodone 30 mg tablet: long-acting opioid must provide ≥300 mg MME per day

*Non-preferred agents with same active ingredient preferred*:
- See Preferred Dosage Form Criteria

*Member with a History of Opioid Use Disorder*
If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill):
1. The request is for one of the following:
   - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
   - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided
2. One of the following is met:
   - Prescribers of both opioid prescription and MOUD (medication for opioid use disorder) are aware of each other and agree to opioid therapy
   - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required

*Renewal Criteria – Approval Duration: 12 months*

- Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).

## Qutenza (capsaicin patch)

| CLINICAL PA REQUIRED |
|---|
| QUTENZA (capsaicin patch) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

## Skeletal Muscle Relaxants

### *Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| baclofen | AMRIX (cyclobenzaprine) TAB 24 HR |
| chlorzoxazone 500 mg | chlorzoxazone 375 mg and 750 mg |
| cyclobenzaprine 5 mg and 10 mg | cyclobenzaprine 7.5 mg |
| dantrolene | cyclobenzaprine ER |
| methocarbamol | carisoprodol |
| orphenadrine ER | carisoprodol-aspirin |
| tizanidine tablets | carisoprodol-aspirin-codeine |
| | DANTRIUM (dantrolene) |
| | LORZONE (chlorzoxazone) |
| | METAXALL (metaxalone) |
| | metaxalone |
| | NORGESIC FORTE (orphenadrine/aspirin/caffeine) |
| | ROBAXIN (methocarbamol) |
| | SKELAXIN (metaxalone) |
| | SOMA (carisoprodol) |
| | tizanidine capsules |
| | ZANAFLEX (tizanidine) |

### *Prior Authorization Criteria*

*Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)*

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone
  - The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.
- All other products:
  - See Preferred Dosage Form Criteria

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications
  - The "Holy Trinity" consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist

### *Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| baclofen solution 5 mg/5 mL | baclofen 25mg/5mL suspension |
| LYVISPAH (baclofen) GRANULE PACKET | FLEQSUVY (baclofen) 25mg/5mL SUSPENSION |

### *Prior Authorization Criteria*

- See Preferred Dosage Form Criteria

# Psychiatry

## ADHD

### Non-Stimulants

### Alpha 2 Agonists

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| clonidine | clonidine ER 0.1 mg | clonidine ER 0.17 mg |
| ONYDA XR (clonidine) | | INTUNIV (guanfacine ER) |
| guanfacine | | |
| guanfacine ER | | |

### *First Fill*

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

### *Therapeutic Duplication*

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time. Guanfacine 4 mg IR or ER can be combined with other strengths to form dosages up to 7 mg per day. Guanfacine IR and ER cannot be combined.
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)

### *Electronic Step Therapy Required*

- Clonidine ER:
  - PA Not Required Criteria: A 30-day supply of clonidine IR has been paid within 90 days prior to clonidine ER's date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of clonidine IR, as evidenced by paid claims or pharmacy printouts.

## Norepinephrine Reuptake Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| atomoxetine | STRATTERA (atomoxetine) |
| **PREFERRED AGENTS (CLINICAL PA REQUIRED)** | |
| QELBREE (viloxazine) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet one of the following:
  - The member has failed a 14-day trial of two stimulants, as evidenced by paid claims or pharmacy printouts.
  - The member has failed a 60-day trial of atomoxetine, as evidenced by paid claims or pharmacy printouts.

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time.

# Stimulants

## Amphetamines

**Solid Dosage Forms**

### *Extended Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dextroamphetamine/amphetamine ER (generic Adderall XR) | ADDERALL XR (dextroamphetamine/amphetamine) |
| dextroamphetamine ER | dextroamphetamine/amphetamine ER (generic Mydayis ER) |
| VYVANSE (lisdexamfetamine) – *Brand Required* | DYANAVEL XR (amphetamine) |
| | lisdexamfetamine |
| | MYDAYIS ER (dextroamphetamine/amphetamine) |

*Immediate Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amphetamine | ADDERALL (dextroamphetamine/amphetamine) |
| dextroamphetamine 2.5 mg, 5 mg, 10 mg | dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg |
| dextroamphetamine/amphetamine | EVEKEO (amphetamine) |
| | methamphetamine |
| | ZENZEDI (dextroamphetamine) |

**Non-Solid Dosage Forms**

*Extended Release*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DYANAVEL XR (amphetamine) SUSPENSION | ADZENYS XR – ODT (amphetamine) |
| lisdexamfetamine chew | VYVANSE (lisdexamfetamine) CHEW TABLET |
| | XELSTRYM (dextroamphetamine) PATCH |

*Immediate Release*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dextroamphetamine 5 mg/5 ml | PROCENTRA (dextroamphetamine) SOLUTION |

## Methylphenidate

**Solid Dosage Forms**

*Extended Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dexmethylphenidate ER | APTENSIO XR (methylphenidate) – *Brand Preferred* |
| methylphenidate CD 30-70 | AZSTARYS (serdexmethylphenidate/dexmethylphenidate) |
| methylphenidate ER tablet (generic Concerta) | CONCERTA (methylphenidate) |
| methylphenidate ER tablet (generic Metadate CD) | FOCALIN XR (dexmethylphenidate) |
| methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg | JORNAY PM (methylphenidate) |
| | methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER) |
| | methylphenidate ER capsule (generic Aptensio XR) |
| | methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg |
| | RELEXXII ER (methylphenidate) |

*Immediate Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| dexmethylphenidate | FOCALIN (dexmethylphenidate) |
| methylphenidate tablet | RITALIN (methylphenidate) |

## Non-Solid Dosage Forms

### *Extended Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DAYTRANA (methylphenidate) PATCH<br>*– Brand Required* | COTEMPLA XR – ODT (methylphenidate) |
| QUILLICHEW ER (methylphenidate) | methylphenidate patch |
| QUILLIVANT XR (methylphenidate) | |

### *Immediate Release*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| methylphenidate chew tablet | METHYLIN (methylphenidate) SOLUTION |
| methylphenidate solution | |

### *Electronic Age Verification*

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent and/or teacher-administered behavior therapy which helps parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

*Non-Preferred Agent Criteria:*

- Amphetamine Non-Solid Dosage Forms Only:
  - The member must have had two 7-day trials of a methylphenidate non-solid dosage form, as evidenced by paid claims or pharmacy printouts..
- Aptensio XR and Azstarys Only – Both of the following must be met:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster, as evidenced by paid claims or pharmacy printouts..
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative, as evidenced by paid claims or pharmacy printouts.
- Jornay PM Only - Both of the following must be met:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives), as evidenced by paid claims or pharmacy printouts.
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).
- Mydayis Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Vyanse or its generic alternative, as evidenced by paid claims or pharmacy printouts.
- All Other Agents: See Preferred Dosage Form Criteria

**References:**


1. Wolraich, Mark L., et al. "Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." *Pediatrics* 144.4 (2019).
2. Hulkower RL, Kelley M, Cloud LK, Visser SN. Medicaid Prior Authorization Policies for Medication Treatment of Attention-Deficit/Hyperactivity Disorder in Young Children, United States, 2015. Public Health Rep. 2017 Nov/Dec;132(6):654-659. doi: 10.1177/0033354917735548. Epub 2017 Oct 26. PMID: 29072963; PMCID: PMC5692165.


## *Therapeutic Duplication*

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for therapeutic duplication requests.

For all stimulants, the following are not payable:
- multiple strengths of a single medication
- amphetamine agent + methylphenidate agent
- multiple long-acting agents
- multiple short acting agents
- non-solid dosage + solid dosage forms

These long-acting stimulants are not allowed with short-acting stimulants:
- Aptensio XR (methylphenidate)
- Adhansia XR (methylphenidate)
- Azstarys (serdexmethylphenidate/dexmethylphenidate)
- Cotempla XR-ODT (methylphenidate)
- Daytrana (methylphenidate)
- Jornay PM (methylphenidate)
- Adderall XR (mixed salts of a single-entity amphetamine product)
- Adzenys XR ODT (amphetamine suspension, extended release)
- Adzenys ER (amphetamine suspension, extended release)
- Dyanavel XR (amphetamine)
- Mydayis (mixed salts of a single-entity amphetamine product)
- Quillivant XR (methylphenidate)
- Vyvanse (lisexamfetamine)
- Vyvanse Chewable (lisexamfetamine)

Amphetamines: One product will be allowed at a time. The following are not payable regimens:
- Dextroamphetamine/Amphetamine ER with Proton Pump Inhibitors
  - Proton pump inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
- Concurrent use of Mydayis and Dyanavel XR with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Methylphenidates: The following are not payable regimens:
- Concurrent use of dexmethylphenidate and methylphenidate
- Concurrent use of Adhansia XR and Azstarys with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

## *Electronic Diagnosis Verification*

- Adderall, Azstarys, Jornay PM, Mydayis: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

*First Fill*

- Long-acting stimulants must be filled with a 14-day supply (or less) if no previous fill within past 99 days

# Antidepressants

## Oral

*Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| amitriptyline | APLENZIN ER (bupropion) |
| amoxapine | CELEXA (citalopram) |
| AUVELITY (dextromethorphan/bupropion) | citalopram capsule 30 mg |
| bupropion | CYMBALTA (duloxetine) |
| bupropion ER | EFFEXOR XR (venlafaxine) |
| bupropion SR | LEXAPRO (escitalopram) |
| citalopram tablet | PAXIL (paroxetine) |
| clomipramine | PAXIL CR (paroxetine) |
| desipramine | PRISTIQ ER (desvenlafaxine) |
| desvenlafaxine ER | PROZAC (fluoxetine) |
| doxepin | REMERON (mirtazapine) |
| duloxetine | sertraline capsule |
| escitalopram | VIIBRYD (vilazodone) |
| fluoxetine | WELLBUTRIN (bupropion) |
| fluvoxamine | WELLBUTRIN SR (bupropion) |
| mirtazapine | WELLBUTRIN XL (bupropion) |
| nefazodone | ZOLOFT (sertraline) |
| nortriptyline | |
| paroxetine | |
| paroxetine ER | |
| protriptyline | |
| sertraline tablet | |
| trazodone | |
| venlafaxine | |
| venlafaxine ER | |
| vilazodone | |
| **High-Cost Options** | |
| FETZIMA (levomilnacipran) | |
| fluoxetine weekly | |
| fluvoxamine ER | |
| imipramine | |
| trimipramine | |
| TRINTELLIX (vortioxetine) | |

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| citalopram oral solution | DRIZALMA (duloxetine) SPRINKLE CAPSULE |
| duloxetine sprinkle capsule | LEXAPRO (escitalopram) ORAL SOLUTION |

| | |
|---|---|
| escitalopram oral solution | PAXIL (paroxetine) ORAL SUSPENSION |
| fluoxetine oral solution | REMERON (mirtazapine) SOLTAB |
| mirtazapine ODT | ZOLOFT (sertraline) ORAL CONCENTRATE |
| sertraline oral concentrate | |
| **High-Cost Options** | |
| paroxetine oral suspension | |

### *Electronic Step Therapy Required*

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg.
  - Trintellix recommended starting dose is 10 mg once daily.
- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service.
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

### *First Fill*

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

### *Therapeutic Duplication*

Please see **Appendix B** for antidepressant cross tapering coverage guidance.

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - bupropion
    - mirtazapine
    - selegiline
- Fetzima, Viibryd, or Trintellix are not allowed with other SSRIs or SNRIs (exceptions: trazodone)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

# Antipsychotics

## Oral

### *Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| aripiprazole | ABILIFY (aripiprazole) |
| clozapine | CLOZARIL (clozapine) |
| FANAPT (iloperidone) | GEODON (ziprasidone) |
| lurasidone | INVEGA ER (paliperidone) |
| olanzapine | LATUDA (lurasidone) |
| quetiapine | RISPERDAL (risperidone) |
| quetiapine ER | SEROQUEL (quetiapine) |
| paliperidone ER | SEROQUEL XR (quetiapine) |
| risperidone | ZYPREXA (olanzapine) |
| ziprasidone | |
| **High-Cost Options** | |

| | |
|---|---|
| CAPLYTA (lumateperone) | olanzapine/fluoxetine |
| COBENFY (xanomeline/trospium) | SYMBYAX (olanzapine/fluoxetine) |
| LYBALVI (olanzapine/samidorphan) | |
| REXULTI (brexpiprazole) | |
| VRAYLAR (cariprazine) | |

*Non-Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| asenapine | RISPERDAL (risperidone) ORAL SOLUTION |
| clozapine ODT | RISPERDAL M-TAB (risperidone) |
| olanzapine ODT | SAPHRIS (asenapine) 2.5 MG |
| risperidone ODT | ZYPREXA ZYDIS (olanzapine) |
| risperidone oral solution | |
| SAPHRIS (asenapine) 5 MG, 10 MG<br>*– Brand Co-Preferred* | |
| **High-Cost Options** | |
| aripiprazole ODT | ABILIFY DISCMELT (aripiprazole) |
| aripiprazole solution | OPIPZA FILM (aripiprazole) |
| SECUADO (asenapine) PATCH | |

*Electronic Step Therapy Required*

Vraylar requires initiation titration:
- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Cobenfy requires initiation titration:
- For 100 mg/20 mg dose: Initiation pack or 2 days of the 50 mg/20 mg capsules is required
- For 125 mg/30 mg dose: Initiation pack or 5 days of the 100 mg/20 mg capsules is required

*Therapeutic Duplication*

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time with the following exceptions:
  - risperidone 0.25 mg, 0.5 mg and 1 mg are allowed with other strengths of risperidone
  - quetiapine 25 mg and 50 mg are allowed with other strengths of quetiapine IR
  - quetiapine 50 mg ER is allowed with other strengths of quetiapine ER
  - olanzapine 2.5 mg is allowed with 10 mg, 15 mg, and 20 mg
  - olanzapine 5 mg is allowed with 7.5 mg and 20 mg

*Underutilization*

- Caplyta, Cobenfy, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherently and will reject on point of sale for late fill

### *First Fill*

- Caplyta, Cobenfy, Fanapt, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

## Long Acting Injectable (LAI)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ABILIFY ASIMTUFII (aripiprazole) | risperidone ER (risperidone microspheres) |
| ABILIFY MAINTENA (aripiprazole) | |
| ARISTADA (aripiprazole lauroxil) | |
| ARISTADA INITIO (aripiprazole lauroxil) | |
| ERZOFRI (paliperidone) | |
| INVEGA HAFYERA (paliperidone) | |
| INVEGA SUSTENNA (paliperidone) | |
| INVEGA TRINZA (paliperidone) | |
| PERSERIS (risperidone) | |
| RISPERDAL CONSTA (risperidone microspheres) *– Brand Required* | |
| RYKINDO ER (risperidone microspheres) | |
| UZEDY (risperidone) | |
| ZYPREXA RELPREVV (olanzapine) | |

### *Electronic Step Therapy Required*

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.

  If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - There is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.
  - Invega Sustenna is being initiated (234 mg x 7 days requires an override for correct billing)

- Aristada Initio: Requires Aristada claim to be billed first.

### *Therapeutic Duplication*

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time.

### *Prior Authorization Criteria*

- See Preferred Dosage Form Criteria

# Benzodiazepines

### *Therapeutic Duplication*

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam.
- One long-acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with:
  - Opioids: Override Criteria Available – See Opioid or Benzodiazepine criteria
  - Xyrem, Xywav
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
- For benzodiazepines only indicated for insomnia: see Insomnia criteria

# Insomnia

## Non-addictive (Non-DEA scheduled) medications

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| hydroxyzine | doxepin |
| mirtazapine | ROZEREM (ramelteon) |
| ramelteon | SILENOR (doxepin) |
| trazodone | |

## Addictive (DEA scheduled) Medications

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| eszopiclone | BELSOMRA (suvorexant) | AMBIEN (zolpidem) |
| zaleplon | zolpidem 10 mg | AMBIEN CR (zolpidem) |
| zolpidem 5 mg | | DAYVIGO (lemborexant) |
| zolpidem ER | | EDLUAR (zolpidem) |
| | | estazolam |
| | | flurazepam |
| | | LUNESTA (eszopiclone) |
| | | QUVIVIQ (daridorexant) |
| | | SECONAL SODIUM (secobarbital) |
| | | temazepam |
| | | triazolam |
| | | zolpidem 7.5 mg |
| | | zolpidem SL tab |

### *Electronic Step Therapy Required*

- Belsomra:
  - PA Not Required Criteria: A 7-day supply of eszopiclone has been paid within 90 days prior to Belsomra's date of service.
  - PA Required Criteria: The member must have failed 7-day trial of eszopiclone, as evidenced by paid claims or pharmacy printouts.
- Zolpidem:

- PA Not Required Criteria: A 7-day supply of zolpidem 5mg or zolpidem ER has been paid within 90 days prior to zolpidem 10mg's date of service.
- PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg or zolpidem ER, as evidenced by paid claims or pharmacy printouts.

### *Prior Authorization Criteria*

Prior Authorization Form – Sedative/Hypnotic

*Initial Criteria – Approval Duration: 3 months*

- Doxepin only
  - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
  - The member's insomnia must be characterized by difficulty with sleep onset.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem IR
    - zaleplon
- temazepam, zolpidem SL, Dayvigo, Quviviq only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
- triazolam, fluazepam, estazolam, seconal sodium, zolpidem 7.5mg only
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

*Renewal Criteria – Approval Duration: 6 months (2 weeks for b*enzodiazepines)

- Other conditions causing sleep issues have been ruled out
- benzodiazepines (temazepam, triazolam, flurazepam, estazolam) only:
  - The member must be undergoing dose tapering

### *Therapeutic Duplication*

- One strength of one medication is allowed at a time
  - Benzodiazepines indicated only for insomnia are not covered with other non-barbiturate insomnia medications or other benzodiazepines
- Sedative/hypnotics are not covered with:
  - Xyrem
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
  - Long-acting benzodiazepines. Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines.
    - Concomitant use can lead to CNS depression.
- Ramelteon, a 1A2 Substrate, is not covered with fluvoxamine, a strong 1A2 inhibitor

- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Sedating benzodiazepines are not covered with opioids

## Non-24-hour Sleep-Wake Disorder

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ramelteon | HETLIOZ (tasimelteon) – *Brand Required* |
| | ROZEREM (ramelteon) |
| | tasimelteon |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
  - Member must be unable to perceive light in either eye.
  - Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance, or medication use, or other neurological or mental disorders.

### *Underutilization*

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

## Smith-Magenis Syndrome

| CLINICAL PA REQUIRED |
|---|
| HETLIOZ (tasimelteon) – *Brand Required* |
| tasimelteon |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- Genetic testing confirms deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation.
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

### *Underutilization*

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

# Pulmonology

## Asthma/COPD

### *Therapeutic Duplication*

o One medication from each class is allowed at time.
- One inhaled steroid
- Long-acting anticholinergic
- Leukotriene pathway inhibitor
- One short-acting beta agonist
- One long-acting beta agonist

### *Electronic Concurrent Medication Required*

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

## Anticholinergics/Beta Agonists Combinations – Short Acting

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| albuterol/ipratropium | DUONEB (albuterol/ipratropium) |
| COMBIVENT RESPIMAT (albuterol/ipratropium) | |

## Anticholinergics/Beta Agonists Combinations – Long Acting

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED STEP 1 AGENTS (PA REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| ANORO ELLIPTA (umeclidinium/vilanterol) | BEVESPI AEROSPHERE (glycopyrrolate/formoterol) | DUAKLIR PRESSAIR (aclidinium/formoterol) |
| STIOLTO RESPIMAT (tiotropium/olodaterol) | | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Non-Preferred Step 1 Agents*
- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

*Non-Preferred Step 2 Agents:*
- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

## Anticholinergics – Long-Acting

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| INCRUSE ELLIPTA (umeclidinium) | SPIRIVA RESPIMAT 1.25 MCG (tiotropium) | tiotropium handihaler |
| SPIRIVA HANDIHALER (tiotropium) – *Brand Required* | | TUDORZA PRESSAIR (aclidinium) |
| SPIRIVA RESPIMAT 2.5 MCG (tiotropium) | | YUPELRI (revefenacin) |

### *Electronic Concurrent Medications Required*

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year

## Beta Agonists – Long-Acting

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| arformoterol | BROVANA (arformoterol) |
| formoterol | PERFOROMIST (formoterol) |
| SEREVENT DISKUS (salmeterol) | |
| STRIVERDI RESPIMAT (olodaterol) | |

## Biologics

### *Anti-IL-5 biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FASENRA (benralizumab) | CINQAIR (reslizumab) – *Medical Billing* |
| | NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR |
| | NUCALA (mepolizumab) VIAL – *Medical Billing* |

### *Anti-IL-4/13 biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| DUPIXENT (dupilumab) | |

*Allergic Asthma-directed biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR | |
| XOLAIR (omalizumab) VIAL – *Medical Billing* | |

*Thymic Stromal Lymphopoietin (TSLP) blocker*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | TEZSPIRE (tezepelumab-ekko) PENS |
| | TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing* |

*Prior Authorization Criteria*

Prior Authorization Form – Asthma

*Initial Criteria – Approval Duration: 6 months*

**For Asthma Only**

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

*Dupixent Only:*
- The member must have an eosinophil count of ≥ 150 cells/mcL or FeNO ≥ 25 ppb within the past year

*Xolair Only:*
- The member has a serum total IgE level, measured before the start of treatment within the past year, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

*Anti-IL-5 biologics:*
- The member has an eosinophil count ≥ 150 cells/mcL within the past year
- *Nucala 40 mg Only:*
  - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Fasenra
- *Nucala 100 mg and Cinqair Only*:
  - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, and Tezspire.

*Tezspire Only:*

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent and Fasenra.

**For COPD Only**

*Dupixent Only:*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 300 cells/mcL within the past year

*Renewal Criteria – Approval Duration: 12 months*

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

## Corticosteroids – Inhaled (Steroid Inhalers)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ARNUITY ELLIPTA (fluticasone) | ALVESCO (ciclesonide) |
| ASMANEX (mometasone) TWISTHALER | ASMANEX HFA (mometasone) |
| budesonide suspension | fluticasone HFA |
| PULMICORT FLEXHALER (budesonide) | fluticasone diskus |
| | PULMICORT RESPULES (budesonide) |
| | QVAR REDIHALER (beclomethasone) |

**GINA and EPR-3 Guidelines – SMART:**

- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
  - Both Symbicort and Dulera are available as HFA products

*Quantity Limits to accommodate SMART therapy:*

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

**References:**


1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." *Journal of Allergy and Clinical Immunology* 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

### *Electronic Age Verification:*

- Fluticasone HFA does not require PA for ages 4 and under

### *Electronic Duration Verification:*

- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses or oral use, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
  - Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

### *Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- *Asmanex HFA and QVAR Redihaler Only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- *fluticasone HFA only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

**References:**


1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
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## Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

### *Solid Dosage Forms*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED STEP 1 AGENTS (PA REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| ADVAIR DISKUS (fluticasone/salmeterol) *– Brand Required* | BREO ELLIPTA (fluticasone/vilanterol) *– Brand Required* | BREYNA (budesonide/formoterol) |
| ADVAIR HFA (fluticasone/salmeterol) *– Brand Required* | | budesonide/formoterol |
| AIRDUO RESPICLICK (fluticasone/salmeterol) *– Brand Required* | | fluticasone/salmeterol |
| DULERA (mometasone/formoterol) | | fluticasone/vilanterol |
| | | SYMBICORT (budesonide/formoterol) |

| | | |
|---|---|---|
| | | *– Brand Required* |
| | | WIXELA INHUB (fluticasone/salmeterol) |

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
  *Quantity Limits to accommodate SMART therapy:*
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

*Non-Preferred Step 1 Agents:*

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

*Non-Preferred Step 2 Agents:*

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For COPD diagnosis only, the member must currently be taking a long acting antimuscarinic agent.

## Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol) | BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have blood eosinophil of ≥ 100 cells/mcL within the past 90 days
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
  - available combination products to achieve this are fluticasone + Anoro Ellipta (umedclidium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incruse Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different

from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agents Criteria:*

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

## Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

| PREFERRED AGENTS (CLINICAL PA REQUIRED) |
|---|
| OHTUVAYRE (ensifentrine) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic, as evidenced by paid claims or pharmacy printouts.
    - The member has a blood eosinophil of < 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic, as evidenced by paid claims or pharmacy printouts.

## Rescue Inhalers

### Albuterol / Levalbuterol

| PREFERRED AGENTS (NO PA REQUIRED) | PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED STEP 2 AGENTS (PA REQUIRED) |
|---|---|---|
| VENTOLIN (albuterol) HFA *– Brand Required* | levalbuterol HFA | albuterol HFA |
| | PROAIR RESPICLICK (albuterol) | PROVENTIL (albuterol) HFA |
| | | XOPENEX (levalbuterol) HFA |

### Rescue Inhaler - Corticosteroid/Short-Acting Beta Agonist (SABA) Combination

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | AIRSUPRA (albuterol/budesonide) |

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief.
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment.

*Quantity Limits to accommodate SMART therapy:*
- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

### *Electronic Step Therapy Required*

- Levalbuterol HFA:
  - PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

### *Electronic Concurrent Medications Required*

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  - The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- Airsupra only:
  - The member must have failed a 30-day trial of albuterol and an ICS/formoterol, as evidenced by paid claims or pharmacy printouts.
- Non-preferred albuterol only: Xeljanz XR Only: See Preferred Dosage Form Criteria

### *Therapeutic Duplication*

- Short acting beta agonist nebulizers and inhalers are not payable together.
  - Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

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2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of

Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232
4. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

# Cystic Fibrosis

## Cystic Fibrosis – Inhaled Antibiotics

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tobramycin (generic Tobi) | ARIKAYCE (amikacin/nebulizer) |
| **PREFERRED AGENTS (PA REQUIRED)** | BETHKIS (tobramycin) |
| TOBI PODHALER (tobramycin) | CAYSTON (aztreonam) |
| | KITABIS PAK (tobramycin/nebulizer) |
| | TOBI (tobramycin) |
| | tobramycin/nebulizer (generic Kitabis) |
| | tobramycin (generic Bethkis) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Arikayce only:
  - The member must be colonized with *Mycobacterium avium* complex (MAC).
  - The member must have not achieved negative sputum cultures after a minimum duration of 6 consecutive months of background treatment with a macrolide, a rifamycin, and ethambutol.
- Cayston only:
  - The member must be colonized with *Pseudomonas aeruginosa.*
  - The member must have had a 28-day trial of tobramycin as evidenced by paid claims or pharmacy printouts.
- Tobi Podhaler only:
  - The member must have failed one 28-day trial of a tobramycin nebulized agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form Criteria

## Cystic Fibrosis – CFTR Modulators

| CLINICAL PA REQUIRED |
|---|
| ALYFTREK (vanzacaftor/tezacaf/deutivacaf) |
| KALYDECO (ivacaftor) |
| ORKAMBI (lumacaftor/ivacaftor) |
| SYMDEKO (tezacaftor/ivacaftor) |
| TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) GRANULES |
| TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) TABLETS |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months (Renewal Approval – 5 years)*

- The member must have a CFTR mutation that the requested medication is FDA-approved to treat

## Cystic Fibrosis – Osmotic Agent

| CLINICAL PA REQUIRED |
|---|
| BRONCHITOL (mannitol) INHALER |

### *Electronic Diagnosis Verification*

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### *Electronic Age Verification*

- The member must be 18 years or older

### *Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*
- Documentation of the Bronchitol Tolerance Test must be submitted

## Idiopathic Pulmonary Fibrosis

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pirfenidone | ESBRIET (pirfenidone) |
| | OFEV (nintedanib) |

### *Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*
- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days.
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

## Interstitial Lung Disease

### *First Line Therapy - Orals*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| azathioprine | |
| cyclophosphamide | |
| mycophenolate mofetil (MMF) | |

### *First Line Therapy - Biologics*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | |

### *Progressive Disease*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab - see Biosimilar Agents | OFEV (nintedanib) |

### *Prior Authorization*

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

## Obstructive Sleep Apnea (OSA)

| CLINICAL PA REQUIRED |
|---|
| ZEPBOUND (tirzepatide) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
- The member must have a diagnosis of moderate to severe OSA defined as apnea-hypopnea index (AHI) > 15 determined by in-lab attended sleep study or polysomnography (PSG)
- The member does not have diabetes type II
- The member must have a diagnosis of obesity (defined as BMI ≥ 30 kg/m2)
- The member must have documentation of participation in a comprehensive weight management program that includes behavioral modification, a reduced-calorie diet, increased physical activity, and pharmacotherapy for at least 6 months with semaglutide.
    - If semaglutide is not tolerated, the pharmacotherapy requirement must be met with phentermine (if phentermine is unable to be used, bupropion, naltrexone, or topiramate may also be used to meet this requirement)
- The member must have failed a 6-month trial of continuous positive airway pressure (CPAP) along with the weight management program.
- If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized

*Renewal Criteria – Approval Duration: 12 months*

- The member has a demonstrated clinical response evidenced by any of the following:
    - Decrease in AHI determined by PSG ≥ 20%, or change in OSA severity status to Remission or Mild Non-Symptomatic OSA (defined as AHI < 5 or AHI 5-14 AND Epworth Sleepiness Scale (ESS) ≤ 10)
    - Weight loss from base line ≥ 10%

# Rheumatology

## Axial Spondyloarthritis/Ankylosing Spondylitis

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| infliximab - see Biosimilar Agents | CIMZIA (certolizumab) VIAL – *Medical Billing* |
| ENBREL (etanercept) | SIMPONI ARIA (golimumab)– *Medical Billing* |
| SIMPONI (golimumab) | |

### Interleukin (IL) – 17 Inhibitors

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TALTZ (ixekizumab)*** | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

### Interleukin (IL)-17A and IL-17F inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | BIMZELX (bimekizumab-bkzx) |

### Janus Kinase (JAK) Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XELJANZ IR (tofacitinib) 5 mg, oral solution | RINVOQ ER (upadacitinib) |
| | XELJANZ IR (tofacitinib) 10 mg |
| | XELJANZ XR (tofacitinib) |

*Electronic Step Therapy Required*

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Cimzia Only: The member must have failed a 90-day trial of TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed a 30-day trial of Xeljanz and a 90-day trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab), as evidenced by paid claims or pharmacy printouts.
- Bimzlex, Cosentyx and Simponi Aria Only: The member must have failed a 30-day trial of Xeljanz and Rinvoq ER, and a 90-day trial of a TNF inhibitor (adalimumab, certolzumab, infliximab, or goliumamab) and Taltz, as evidenced by paid claims or pharmacy printouts.
- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form Criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Behçet syndrome

*Phosphodiesterase 4 (PDE4) Inhibitor*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| OTEZLA (apremilast) | |

**TNF Inhibitors**

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | |
| infliximab - see Biosimilar Agents | |

*Prior Authorization Criteria*

- See Medications that cost over $3000/month criteria

## Cryopyrin Associated Periodic Syndrome (CAPS)

*Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome*

*Interleukin (IL) -1 Receptor Inhibitors*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KINERET (anakinra) | ARCALYST (rilonacept) |
| | ILARIS (canakinumab) – *Medical Billing* |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms:
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

## Familial Mediterranean Fever (FMF)

### Colchicine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| colchicine tablets | colchicine capsules |

| | |
|---|---|
| | GLOPERBA (colchicine) ORAL SOLUTION |
| | MITIGARE (colchicine) CAPSULE |

## Interleukin (IL) -1 Receptor Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KINERET (anakinra) | ARCALYST (rilonacept) |
| | ILARIS (canakinumab) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

# Giant Cell Arteritis (Temporal Arteritis)

## Interleukin (IL) -6 Receptor Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | |

### *Prior Authorization Criteria*

- See Medications that cost over $3000/month criteria

# Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

*Symptomatic Treatment*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NSAIDs | |
| glucocorticoids | |
| KINERET (anakinra) | |

*Preventative Treatment*

| CLINICAL PA REQUIRED |
|---|
| ILARIS (canakinumab) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.

- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

# Juvenile Idiopathic Arthritis

## Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

### Interleukin (IL) – 17 Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | |
| ENBREL (etanercept) | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*
- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.

## Juvenile Idiopathic Arthritis – Polyarticular Course

### Interleukin (IL) -6 Receptor Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | KEVZARA (sarilumab) |

### Janus Kinase (JAK) Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XELJANZ IR (tofacitinib) 5 MG TABLET, SOLUTION | RINVOQ ER TABLET, SOLUTION |
| | XELJANZ IR (tofacitinib) 10 MG TABLET |
| | XELJANZ XR (tofacitinib) |

### T-cell Costimulation Blocker

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ORENCIA (abatacept) – 125 mg/mL syringe | ORENCIA (abatacept)<br>- 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes |
| | ORENCIA (abatacept) – *Medical Billing* |

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| ENBREL (etanercept) | CIMZIA (certolizumab) VIAL – *Medical Billing* |
| | SIMPONI ARIA (golimumab) – *Medical Billing* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Xeljanz Oral Solution Only: The member has failed a 3-month trial of a TNF inhibitor and Orencia, as evidenced by paid claims or pharmacy print outs.
- Rinvoq ER and Simponi Aria Only: The member has failed a 3-month trial of a TNF inhibitor and Orencia, and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Kevzara Only: The member has failed a 3-month trial of a TNF inhibitor and tocilizumab, as evidenced by paid claims or pharmacy print outs.
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review)

## Juvenile Chronic Arthritis – Systemic Onset

### Interleukin (IL) -1 Receptor Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | ILARIS (canakinumab) – *Medical Billing* |

### Interleukin (IL) -6 Receptor Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | |

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | |
| ENBREL (etanercept) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- Ilaris Only: The member has failed a 3-month trial of tocilizumab, as evidenced by paid claims or pharmacy print outs.

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# Osteoporosis

## Antiresorptive Agents

### *Bisphosphonates*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| alendronate | ACTONEL (risedronate) |
| alendronate oral solution | ATELVIA (risedronate DR) |

| | |
|---|---|
| BONIVA (ibandronate) – *Medical Billing* | FOSAMAX (alendronate) |
| ibandronate – *Medical Billing* | FOSAMAX D (alendronate/vitamin D) |
| RECLAST (zolendronic acid) – *Medical Billing* | risedronate DR |
| risedronate IR | |
| zoledronic acid – *Medical Billing* | |

### *Prior Authorization Criteria*

- Risedronate DR Only: See Preferred Dosage Form criteria

### *Calcitonins*

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| calcitonin, salmon nasal spray++ | calcitonin, salmon vial |
| MIACALCIN (calcitonin, salmon) VIAL++ – *Medical Billing* | |

++ Clinically Non-Preferred: An FDA advisory panel concluded that the benefits of calcitonin do not outweigh its potential risks as an osteoporosis drug due to increased risk of malignancy. Bisphosphonates are more effective agents.

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- The member must be experiencing pain from an acute osteoporotic fracture

### *Estrogen Agonist/Antagonist*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| raloxifene | EVISTA (raloxifene) |

### *Monoclonal Antibodies*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| PROLIA (denosumab) – *Medical Billing* | |

## Anabolic Agents

### *Parathyroid Hormone (PTH)*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FORTEO (teriparatide) – *Brand Required* | teriparatide |

### *PTH-related protein*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | TYMLOS (abaloparatide) |

### *Monoclonal Anti-sclerostin Antibody*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| EVENITY (romosozumab-aqqg) – *Medical Billing* | |

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 2 years (1 year for Evenity)*

- The member must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - teriparatide
- Member must be at high risk of fracture, confirmed by at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of −2.5 or lower at the femoral neck or spine
  - The member has a T-score of between −1.0 and −2.5 at the femoral neck or spine and a ten-year hip fracture risk of ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

# Polymyalgia Rheumatica

## Interleukin (IL) -6 Receptor Inhibitors

| CLINICAL PA REQUIRED |
|---|
| KEVZARA (sarilumab) |

*Prior Authorization Criteria*

- See Medications that cost over $3000/month criteria

# Psoriatic Arthritis

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| infliximab - see Biosimilar Agents | CIMZIA (certolizumab) VIAL – *Medical Billing* |
| ENBREL (etanercept) | SIMPONI ARIA (golimumab)– *Medical Billing* |
| SIMPONI (golimumab) | |

### Phosphodiesterase 4 (PDE4) Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| OTEZLA (apremilast) | |

### Janus Kinase (JAK) Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XELJANZ IR (tofacitinib) 5 mg, oral solution | RINVOQ ER (upadacitinib) |
| | XELJANZ IR (tofacitinib) 10 mg |
| | XELJANZ XR (tofacitinib) |

### T-cell Costimulation Blocker

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ORENCIA (abatacept) – 125 mg/mL syringe | ORENCIA (abatacept) – *Medical Billing* |
| | ORENCIA (abatacept)<br>– 50 mg/0.4mL, 87.5 mg/0.7 mL syringe |

### Interleukin (IL) – 17 Inhibitors

| PREFERRED AGENTS (ELECTRONIC STEP REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TALTZ (ixekizumab) | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

### Interleukin (IL)-17A and IL-17F inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | BIMZELX (bimekizumab-bkzx) |

### Interleukin (IL)-23p19 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SKYRIZI (risankizumab-rzaa) |
| | TREMFYA (guselkumab) |

### Interleukin (IL)-12/IL-23 Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SELARSDI (ustekinumab-aekn) |
| | STELARA (ustekinumab) |
| | STEQEYMA (ustekinumab-stba) |
| | ustekinumab-ttwe |
| | WEZLANA (ustekinumab-auub) |
| | YESINTEK (ustekinumab-kfce) |

*Electronic Step Therapy Required*

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

**Pediatric Members:**

- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

**Adult Members:**

- Cimzia, Rinvoq ER, Cosentyx: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
- Bimzelx, Cosentyx, Simponi Aria, Skyrizi and Tremfya Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
  - Rinvoq ER

- Ustekinumab Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - TNF inhibitor
    - Interleukin (IL) – 17 inhibitor
    - Interleukin (IL) - 23p19 Inhibitor
    - Rinvoq ER
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why self-administered agents cannot be used (subject to clinical review).
- All other Agents: See Preferred Dosage Form Criteria

## Rheumatoid Arthritis

### Anti-CD20 Monoclonal Antibodies

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| rituximab - see Biosimilar Agents | |

### Interleukin (IL) -1 Receptor Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KINERET (anakinra) | |

### Interleukin (IL) -6 Receptor Inhibitors

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| tocilizumab – See Biosimilar Agents | KEVZARA (sarilumab) |

### Interleukin (IL) – 17 Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | COSENTYX (secukinumab) |
| | COSENTYX (secukinumab) – *Medical Billing* |

### Janus Kinase (JAK) Inhibitor

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| XELJANZ IR (tofacitinib) 5 mg, oral solution | OLUMIANT (baricitinib) |
| | RINVOQ ER (upadacitinib) |
| | XELJANZ IR (tofacitinib) 10 mg |
| | XELJANZ XR (tofacitinib) |

### T-cell Co-stimulation Blocker

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ORENCIA (abatacept) – 125 mg/mL syringe | ORENCIA (abatacept) – *Medical Billing* |

### TNF Inhibitors

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab - see Biosimilar Agents | CIMZIA (certolizumab) SYRINGE |
| infliximab - see Biosimilar Agents | CIMZIA (certolizumab) VIAL – *Medical Billing* |
| ENBREL (etanercept) | SIMPONI ARIA (golimumab)– *Medical Billing* |
| SIMPONI (golimumab) | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - Orencia
  - Xeljanz
- Cosentyx, Kevzara, Rinvoq ER and Simponi Aria only: The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - Orencia
  - Xeljanz
  - tocilizumab
- Xeljanz IR 10mg, Xeljanz XR only: See Preferred Dosage Form criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Adult-Onset Still's Disease

### *Interleukin (IL) -1 Receptor Inhibitors*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KINERET (anakinra) | ILARIS (canakinumab) – *Medical Billing* |

### *Infliximab*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| infliximab – See Biosimilar Agents | |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:

## Tumor Necrosis Factor Receptor Associated Periodic Syndrome

| CLINICAL PA REQUIRED |
|---|
| ILARIS (canakinumab) |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- One of the following must be met (A or B):

A. Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
B. Both of the following:
   - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
   - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

# Substance Use

## Nicotine / Tobacco Dependence Treatment

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| bupropion SR | CHANTIX (varenicline) |
| nicotine lozenge | NICODERM CQ (nicotine) PATCH |
| nicotine patch | NICORETTE (nicotine polacrilex) GUM |
| nicotine polarcrilex gum | ZYBAN (bupropion SR) |
| NICOTROL (nicotine polacrilex) SPRAY | |
| varenicline | |

### *Concurrent Medication Required*

- Short-acting nicotine agents (nasal spray, lozenge, and gum) require concurrent nicotine patch, bupropion SR (generic Zyban), or varenicline since better outcomes are associated with concurrent use of short-acting and long-acting tobacco cessation products.
  - A total of 14 days of nicotine patch, bupropion SR (generic Zyban), or varenicline must be paid within 40 days prior to nicotine nasal spray, lozenge, or gum's date of service.

Clinically Important Information: Bupropion SR (generic Zyban) takes 5 to 7 days to reach steady state. It is recommended to start one week before target quit date. NRT products are allowed in addition to bupropion SR to bridge therapy until bupropion SR becomes effective and for concurrent use.

### *Electronic Duration Verification*

- A total of 12 consecutive weeks will be covered for all other products, every 6 months.

  Varenicline or bupropion SR (generic Zyban): If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - Patient is abstinent from tobacco.
  - Treatment duration is requested to be extended to 24 consecutive weeks.

### *Therapeutic Duplication*

- Nicotine gum, lozenge, and spray will not be paid concurrently.
- Bupropion SR (generic Zyban) will not be paid with other forms of bupropion.

### *Underutilization*

- Nicotine Patch, varenicline, and bupropion SR (generic Zyban) must be used adherently and will reject on point of sale for late fill.

# Opioid Use Disorder

## Alpha-2 Adrenergic Agonists

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| clonidine | lofexidine |
| guanfacine | LUCEMYRA (lofexidine) – *Brand Required* |

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Opioid Antagonist

| PREFERRED AGENTS (NO PA REQUIRED) |
|---|
| naltrexone tablets |
| VIVITROL (naltrexone microspheres) INJECTION |

## Opioid Reversal Medications

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| KLOXXADO (naloxone) NASAL SPRAY | ZIMHI (naloxone) SYRINGE |
| nalmefene injection | |
| naloxone nasal spray | |
| naloxone injection | |
| NARCAN (naloxone) NASAL SPRAY – *Brand Co-Preferred* | |
| OPVEE (nalmefene) NASAL SPRAY | |
| REXTOVY (naloxone) NASAL SPRAY – *Brand Co-Preferred* | |

### *Electronic Duration Verification*

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for an opioid overdose. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

# Opioid Partial Agonist

## *Electronic Step Therapy Required*

- A total of 28 days of Sublocade 300 mg must be paid within 60 days prior to Sublocade 100 mg date of service.

Per Sublocade package insert:

| Established Transmucosal Buprenorphine Doses | Initial Dose of TM Buprenorphine | Injection #1 | Injection #2 | Maintenance Dose |
|---|---|---|---|---|
| N/A, none | 4 mg[b] | 300 mg | 100 mg[a] | 100 mg |
| 8 – 24 mg/day | N/A | 300 mg | 300 mg | 100 mg |
| [a]For patients receiving 8 mg – 18 mg daily TM buprenorphine still experiencing craving or withdrawal symptoms after the initial 300-mg dose, consider giving 300 mg as the second dose<br>[b]On induction day, additional transmucosal buprenorphine may be administered as needed to manage withdrawal symptoms. Monitor patients for 1 hour to confirm tolerability before administering the first injection of Sublocade | | | | |

## *Therapeutic Duplication*

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
    - methadone
    - carisoprodol
    - opioids

- Opioid full agonist requested with member with history of opioid use disorder.
    - If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill)
        1. The request is for one of the following:
            - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
            - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided.
        2. One of the following is met:
            - Prescribers of both opioid prescription and MOUD (medications for opioid use disorder) are aware of each other and agree to opioid therapy.
            - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required.

- Opioid partial agonist injection + oral overlap

  Please call for an override by calling provider relations at 1-800-755-2604 to request a 4 month overlap period with oral buprenorphine/naloxone while initiating long-acting injectable buprenorphine (until the therapeutic levels are achieved).

## Mono Product

### *Oral Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| | buprenorphine tablets++ |

++ Clinically Non-Preferred: Naloxone is added to buprenorphine to prevent misuse. When taken correctly, a baby will have little to no absorption of naloxone which a growing body of evidence show is safe. Taking combination product during pregnancy or breastfeeding means that products don't need to be switched to a different medication after the baby is born during this high anxiety time. Risk of withdrawal to a neonate is a labeled warning on each product. Pregnancy and breastfeeding are not listed as contraindications on either product.

**References**:


1. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.
2. Perry, Briana N. MD; Vais, Simone BA; Miller, Melissa BA; Saia, Kelley A. MD. Buprenorphine-Naloxone Versus Buprenorphine for Treatment of Opioid Use Disorder in Pregnancy [07E]. Obstetrics & Gynecology 135():p 51S, May 2020. | DOI: 10.1097/01.AOG.0000663444.50960.74
3. Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.


### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 1 year*

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
  - Allergy to oral naloxone is extremely rare and must be well documented.
  - Any request for transmucosal buprenorphine should include justification why long-acting injectable buprenorphine can't be used
    - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
    - Stability will not be approved as clinical justification, although limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product – maximum of 7 days for Sublocade, and 1 dose for Brixadi

### *Non-Oral Agents*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| BRIXADI (buprenorphine) | |
| SUBLOCADE (buprenorphine) | |

## Combination Product

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| buprenorphine-naloxone tablets | BUNAVAIL FILM (buprenorphine/naloxone) |
| | buprenorphine/naloxone film |
| | SUBOXONE FILM (buprenorphine/naloxone) |
| | ZUBSOLV (buprenorphine/naloxone) |

### *Prior Authorization Criteria*

- See Preferred Dosage Form Criteria

# Biosimilar Agents:

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 90-day trial of each preferred medication, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Adalimumab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| adalimumab-adaz | ABRILADA (adalimumab-afzb) |
| adalimumab-adbm – labeler 00597 | adalimumab-aacf |
| adalimumab-fkjp | adalimumab-aaty |
| HADLIMA (adalimumab-bwwd) | adalimumab-adbm – labeler 82009 |
| HULIO (adalimumab-fkjp) | adalimumab-ryvk |
| HUMIRA (adalimumab) | AMJEVITA (adalimumab-atto) |
| SIMLANDI (adalimumab-ryvk) | CYLTEZO (adalimumab-abdm) |
| | HYRIMOZ (adalimumab-adaz) |
| | IDACIO (adalimumab-aacf) |
| | YUFLYMA (adalimumab-aaty) |
| | YUSIMRY (adalimumab-aqvh) |

## Bevacizumab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| MVASI (bevacizumab – awwb) – *Medical Billing* | ALYMSYS (bevacizumab – maly) – *Medical Billing* |
| ZIRABEV (bevacizumab – bvzr) – *Medical Billing* | AVASTIN (bevacizumab) – *Medical Billing* **C9257 for ophthalmology injections does not require PA.* |
| | VEGZELMA (bevacizumab – acdc) – *Medical Billing* |

## Filgrastim

*Medical Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| GRANIX (TBO-filgrastim) – *Medical Billing* | NEUPOGEN (filgrastim) – *Medical Billing* |
| NIVESTYM (filgrastim-aafi) – *Medical Billing* | RELEUKO (filgrastim-ayow) – *Medical Billing* |
| ZARXIO (filgrastim-sndz) – *Medical Billing* | |

*Pharmacy Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NEUPOGEN (filgrastim) | GRANIX (TBO-filgrastim) |
| RELEUKO (filgrastim-ayow) | NIVESTYM (filgrastim-aafi) |

| | |
|---|---|
| | ZARXIO (filgrastim-sndz) |

## Pegfilgrastim

*Medical Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| NEULASTA (pegfilgrastim) – *Medical Billing* | FULPHILA (pegfilgrastrim-jmdb) – *Medical Billing* |
| NEULASTA ONPRO (pegfilgrastim) – *Medical Billing* | FYLNETRA (pegfilgrastim -pbbk) – *Medical Billing* |
| NYVEPRIA (pegfilgrastrim–apgf) – *Medical Billing* | STIMUFEND (pegfilgrastim-fpgk) – *Medical Billing* |
| UDENYCA ONBODY (pegfligrastim-cbqv) – *Medical Billing* | UDENYCA (pegfligrastim-cbqv) – *Medical Billing* |
| | ZIEXTENZO (pegfilgrastim-bmez) – *Medical Billing* |

*Pharmacy Billing*

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FULPHILA (pegfilgrastrim-jmdb) | NEULASTA (pegfilgrastim) |
| FYLNETRA (pegfilgrastim -pbbk) | NYVEPRIA (pegfilgrastim–apgf) |
| NEULASTA ONPRO (pegfilgrastim) | STIMUFEND (pegfilgrastim-fpgk) |
| UDENYCA ONBODY (pegfligrastim-cbqv) | UDENYCA (pegfligrastim-cbqv) |
| | ZIEXTENZO (pegfilgrastim-bmez) |

## Infliximab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| AVSOLA (infliximab-axxq) – *Medical Billing* | infliximab – *Medical Billing* |
| INFLECTRA (infliximab-dyyb) – *Medical Billing* | RENFLEXIS (infliximab-abda) – *Medical Billing* |
| | REMICADE (infliximab) – *Medical Billing* |
| | ZYMFENTRA (infliximab-dyyb) |

## Insulin Glargine - Lantus

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| LANTUS U-100 (insulin glargine) – *Brand Required* | BASAGLAR KWIKPEN U-100 (insulin glargine) |
| | BASAGLAR TEMPO PEN U-100 (insulin glargine) |
| | insulin glargine-yfgn U-100 (generic Semglee) |
| | REZVOGLAR U-100 (insulin glargine-aglr) |
| | SEMGLEE U-100 (insulin glargine) YFGN |

## Insulin Lispro - Humalog

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| HUMALOG U-100 (insulin lispro) CARTRIDGE | ADMELOG (insulin lispro) |
| insulin lispro U-100 pen, jr pen | HUMALOG (insulin lispro) VIAL, PEN, TEMPO |
| | insulin lispro vial |

| | |
|---|---|
| | LYUMJEV U-100 (insulin lispro-aabc) |
| | LYUMJEV U-200 (insulin lispro-aabc) |
| | LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc) |

## Ranibizumab

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CIMERLI (ranibizumab-eqrn) – *Medical Billing* | BYOOVIZ (ranibizumab-nuna) – *Medical Billing* |
| | LUCENTIS (ranibizumab) – *Medical Billing* |

## Rituximab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| RIABNI (rituximab-arrx) – *Medical Billing* | RITUXAN (rituximab) – *Medical Billing* |
| RUXIENCE (rituximab-pvvr) – *Medical Billing* | |
| TRUXIMA (rituximab-abbs) – *Medical Billing* | |

## Tocilizumab

| PREFERRED AGENTS (CLINICAL PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE | ACTEMRA (tocilizumab) ACTPEN, SYRINGE |
| TYENNE (tocilizumab-aazg) VIAL – *Medical Billing* | ACTEMRA (tocilizumab) VIAL – *Medical Billing* |
| | TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing* |

## Trastuzumab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| TRAZIMERA (trastuzumab-qyyp) – *Medical Billing* | KANJINTI (trastuzumab-anns) – *Medical Billing* |
| | HERCESSI (trastuzumab-strf) – *Medical Billing* |
| | OGIVRI (trastuzumab-dkst) – *Medical Billing* |
| | ONTRUZANT (trastuzumab-dttb) – *Medical Billing* |
| | HERZUMA (trastuzumab-pkrb) – *Medical Billing* |
| | HERCEPTIN (trastuzumab) – *Medical Billing* |

## Ustekinumab

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| | SELARSDI (ustekinumab-aekn) |
| | SELARSDI (ustekinumab-aekn) – *Medical Billing* |
| | STELARA (ustekinumab) |
| | STELARA (ustekinumab) – *Medical Billing* |
| | STEQEYMA (ustekinumab-stba) |
| | STEQEYMA (ustekinumab-stba) -- *Medical Billing* |
| | ustekinumab-ttwe |
| | ustekinumab-ttwe – *Medical Billing* |
| | WEZLANA (ustekinumab-auub) |

| | |
|---|---|
| | WEZLANA (ustekinumab-auub) – *Medical Billing* |
| | YESINTEK (ustekinumab-kfce) |
| | YESINTEK (ustekinumab-kfce) -- *Medical Billing* |

# Preferred Dosage Form Criteria List:

*Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Azathioprine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| azathioprine 50 mg | azathioprine 75 mg |
| | azathioprine 100 mg |

## Bendamustine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| bendamustine 25 mg and 100 mg vials – *Medical Billing* | BELRAPZO (bendamustine) 100 MG/4 ML VIALS – *Medical Billing* |
| BENDEKA (bendamustine) 100 MG/4 ML VIALS – *Medical Billing* | bendamustine 100 mg/4 mL vials – *Medical Billing* |
| | VIVIMUSTA (bendamustine) 100 MG/4 ML VIALS – *Medical Billing* |

## Brisdelle (paroxetine)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| paroxetine tablets | paroxetine mesylate 7.5 mg capsules |
| | PEXEVA (paroxetine mesylate) |

## butalbital-acetaminophen-caffeine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| butalbital-acetaminophen-caffeine tablets | butalbital-acetaminophen-caffeine capsules |
| VTOL LQ (butalbital-acetaminophen-caffeine) SOLUTION | ESGIC (butalbital-acetaminophen-caffeine) TABLET |
| | FIORICET (butalbital-acetaminophen-caffeine) CAPSULES |
| | ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES |

## citalopram

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| citalopram tablets | citalopram capsules |
| citalopram solution | |

## colchicine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| colchicine tablet | colchicine capsule |
| | GLOPERBA (colchicine) ORAL SOLUTION |
| | LODOCO (colchicine) TABLET |
| | MITIGARE (colchicine) CAPSULE |

## cyanocobalamin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| cyanocobalamin injection | NASCOBAL (cyanocobalamin) NASAL SPRAY |

## epinephrine

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| epinephrine – labeler 49502 | AUVI-Q (epinephrine) |
| EPIPEN (epinephrine) – *Brand Co-Preferred* | epinephrine – labeler 00093, 00115 |
| EPIPEN (epinephrine) JUNIOR– *Brand Co-Preferred* | NEFFY (epinephrine) |

*Electronic Duration Verification*

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for an anaphylactic episode

## gabapentin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| gabapentin | gabapentin ER |
| | GABARONE (gabapentin) |
| | GRALISE (gabapentin) |
| | HORIZANT (gabapentin) |

## Jadenu (deferasirox)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| deferasirox tablet for suspension | EXJADE (deferasirox tablet for suspension) |
| deferasirox tablets | deferasirox sprinkle |
| | JADENU (deferasirox) SPRINKLE |
| | JADENU (deferasirox) TABLETS |

## Kits

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| FDA approved products prescribed separately | CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor) |
| | CENTANY AT (mupirocin) |
| | CICLOPIROX (ciclopirox/urea/camphor/methol) |
| | CICLODAN (ciclopirox/urea/camphor/methol) |
| | CICLODAN (ciclopirox/skin cleanser 28) |
| | CLINDACIN ETZ (clindamycin phos/skin clnsr 19) |
| | CLINDACIN PAC (clindamycin phos/skin clnsr 19) |
| | CLINDAVIX (clindamycin/dimethacone/zinc oxide) |
| | CLOBETEX (clobetasol/desloratadine) |
| | CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine) |
| | DERMACINRX ARM PAK (lidocaine/dimethacone) |
| | DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin) |
| | DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102) |
| | DERMACINRX SILAPAK (triamcinolone/dimeth/silicone) |
| | DERMACINRX SILAZONE (triamcinolone/silicones) |
| | DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth) |
| | DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc) |
| | DERMACINRX ZRM PAK (lidocaine/dimethicone) |
| | DERMALID 5% PATCH (lidocaine/elastic bandage) |
| | ELLZIA PAK (triamcinolone/dimethicone) |
| | ESOMEP-EZS KIT (esomeprazole mag/glycerin) |
| | ECONASIL (econazole/gauze/silicone) |
| | FLUOPAR (fluocinonide/dimethacone) |
| | FLUOVIX PLUS (fluocinonide/silicone,adhesive) |
| | GABACAINE KIT (gabapentin/lidocaine) |
| | INAVIX (diclofenac/capsaicin) |
| | INFAMMACIN (diclofenac/capsicum) |
| | KETODAN (ketoconazole/skin cleanser 28) |
| | LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape) |
| | LIDOTIN (gabapentin/lidocaine/silicone) |
| | LIPRITIN (gabapentin/lidocaine/prilocaine/dressing) |
| | LOPROX (ciclopirox/skin cleanser No. 40) |
| | MIGRANOW KIT (sumatriptan/menthol/camphor) |
| | MORGIDOX (Doxycycline/skin cleanser No. 19) |
| | NAPROTIN (naproxen/capsicum) |
| | NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine) |
| | NUVAKAAN KIT (lidocaine/prilocaine/silicone) |
| | NUSURGEPAK (mupirocin/chlorhexidine/dimethacone) |
| | NUTRIARX (Triamcinolone/dimethacone/silicone) |
| | PRILO PATCH KIT (lidocaine/prilocaine) |
| | PRIZOTRAL II (lidocaine/prilocaine/lidocaine) |
| | PRO DNA MEDICATED COLLECTION (lidocaine/glycerin) |

| | |
|---|---|
| | REVIVASIL (gel pad/dmc/dime/dec/oct/vit E) KIT |
| | SALEX (salicylic acid/ceramide comb 1) CREAM KIT |
| | SALEX (salicylic acid/ceramide comb 1) LOTION KIT |
| | SILAZONE-II KIT (triamcinolone aceton/silicones) |
| | SOLARAVIX (Diclofenac/silicone, adhesive) |
| | SUMADAN KIT (sulfacetamide/sulfur/cleansr23) |
| | SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23) |
| | TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate) |
| | TRIVIX (Triamcinolone/dimethacone/silicone) |
| | TRIXYLITRAL (diclofenac/lidocaine/tape) |
| | XRYLIX 1.5% KIT (diclofenac/kinesiology tape) |
| | ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive) |

## lactulose

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CONSTULOSE (lactulose) solution | KRISTALOSE (lactulose) PACKET |
| ENULOSE (lactulose) solution | lactulose packet |
| lactulose solution | |

## metformin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| metformin ER | FORTAMET (metformin) |
| RIOMET (metformin) ORAL SOLUTION | GLUMETZA (metformin) |
| RIOMET ER (metformin) ORAL SOLUTION | metformin ER gastric retention 24 hr |
| | metformin ER osmotic |

## methotrexate

**Required trial duration**: 6 weeks

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| methotrexate | OTREXUP (methotrexate) AUTO-INJECTOR |
| JYLAMVO (methotrexate) SOLUTION | RASUVO (methotrexate) AUTO-INJECTOR |
| XATMEP (methotrexate) SOLUTION | REDITREX (methotrexate) SYRINGE |
| | TREXALL (methotrexate) TABLET |

## mycophenolate mofetil

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| mycophenolate mofetil | CELLCEPT (mycophenolate mofetil) |
| | MYHIBBIN (mycophenolate mofetil) |

## montelukast

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| montelukast chewable tablets | montelukast granules |
| montelukast tablets | |

*Electronic Age Verification*

- Montelukast granules are preferred for ages 1 and under

## mupirocin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| mupirocin ointment | mupirocin calcium cream |

## nitisinone

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ORFADIN (nitisinone) 2 MG, 5 MG, 10 MG CAPSULE | NITYR (nitisinone) TABLET |
| ORFADIN (nitisinone) SUSPENSION | ORFADIN (nitisinone) 20 MG CAPSULE |
| | |

## nitroglycerin

**Required trial duration**: 1 dose while on preventative medication

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| nitroglycerin sublingual tablets | GONITRO (nitroglycerin) SUBLINGUAL PACKET |
| | nitroglycerin spray |
| | NITROLINGUAL (nitroglycerin) SPRAY |

## Nocdurna (desmopressin)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| desmopressin | NOCDURNA (desmopressin) |

## Pregabalin

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| pregabalin | LYRICA (pregabalin) |
| | LYRICA CR (pregabalin) |
| | pregabalin ER |

## Procysbi (cysteamine)

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| CYSTAGON (cysteamine) | PROCYSBI (cysteamine) |
| | PROCYSBI GRANULES (cysteamine) |

## Steroids – Oral

Agamree and Emflaza: See Duchenne Muscular Dystrophy Criteria on this document

Eohilia: See Eosinophilic Esophagitis on this document

Tarpeyo: See Tarpeyo Criteria on this document

Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|

| | |
|---|---|
| budesonide 3 mg EC capsules | AGAMREE (vamorolone) |
| cortisone | ALKINDI (hydrocortisone) SPRINKLE CAPSULE |
| dexamethasone | budesonide 9 mg ER tablet |
| hydrocortisone | deflazacort |
| methylprednisone | EOHILIA (budesonide) |
| prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml | EMFLAZA (deflazacort) – *Brand Required* |
| prednisone solution | HEMADY (dexamethasone) |
| prednisone tablets | MILLIPRED (prednisolone) |
| | ORTIKOS (budesonide) |
| | prednisone intensol |
| | prednisolone sodium phosphate ODT |
| | prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution |
| | RAYOS (prednisone) |
| | TAPERDEX (dexamethasone) |
| | UCERIS (budesonide) |

## ursodiol

| PREFERRED AGENTS (NO PA REQUIRED) | NON-PREFERRED AGENTS (PA REQUIRED) |
|---|---|
| ursodiol capsule | RELTONE (ursodiol) CAPSULE |
| ursodiol tablet | URSO 250 (ursodiol) TABLET |
| | URSO FORTE (ursodiol) TABLET |

# Preferred Diabetic Supply List (PDSL)

### *Electronic Concurrent Medications Required*

- One of the following must apply:
  - A total of a 25-day supply of one of the following must be paid within 150 days prior to diabetic supplies' date of service:
    - agents that cause hypoglycemia (insulin or sulfonylureas)
    - agents that indicate pregnancy (folic acid or prenatal vitamins)

### *Prior Authorization Criteria*

*Initial Criteria – Approval Duration: 6 months*

- For coverage of blood glucose monitoring devices for those not meeting electronic concurrent medication required criteria above, the member has one of the following (A or B):
  - A. Recurrent hypoglycemia and the test strips are prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)
  - B. A diagnosis of diabetes and meet **one of the following** criteria:
    1. Newly diagnosed within the last 6 months
    2. Acutely ill
    3. Significant change in health status causing blood sugar variability
    4. Currently pregnant

The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

## Test Strips

### *Quantity Limits*

- 200 test strips are covered every 30 days

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Roche Diabetes Care, Inc. | 65702-0711-10 | Accu-Chek Guide Test Strip |
| Roche Diabetes Care, Inc. | 65702-0712-10 | Accu-Chek Guide Test Strip |

## Meters

### *Quantity Limits*

- 1 meter is covered every 365 days

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Roche Diabetes Care, Inc. | 65702-0731-10 | Accu-Chek Guide Me Glucose Meter |
| Roche Diabetes Care, Inc. | 65702-0729-10 | Accu-Chek Guide Monitor System |

## InPen

*Quantity Limits*

- 1 InPen is covered every 365 days

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Minimed Distribution Corporation | 62088-0000-31 | InPen Smart Insulin Pen (Humalog - Blue) |
| Minimed Distribution Corporation | 62088-0000-32 | InPen Smart Insulin Pen (Humalog - Grey) |
| Minimed Distribution Corporation | 62088-0000-33 | InPen Smart Insulin Pen (Humalog - Pink) |
| Minimed Distribution Corporation | 62088-0000-34 | InPen Smart Insulin Pen (Novolog or Fiasp – Blue) |
| Minimed Distribution Corporation | 62088-0000-35 | InPen Smart Insulin Pen (Novolog or Fiasp – Gray) |
| Minimed Distribution Corporation | 62088-0000-36 | InPen Smart Insulin Pen (Novolog or Fiasp – Pink) |
| Minimed Distribution Corporation | 63000-0827-15 | InPen Smart Insulin Pen (Humalog - Blue) |
| Minimed Distribution Corporation | 63000-0827-16 | InPen Smart Insulin Pen (Humalog - Grey) |
| Minimed Distribution Corporation | 63000-0827-17 | InPen Smart Insulin Pen (Humalog - Pink) |
| Minimed Distribution Corporation | 63000-0827-18 | InPen Smart Insulin Pen (Novolog or Fiasp – Blue) |
| Minimed Distribution Corporation | 63000-0827-19 | InPen Smart Insulin Pen (Novolog or Fiasp – Gray) |
| Minimed Distribution Corporation | 63000-0827-20 | InPen Smart Insulin Pen (Novolog or Fiasp – Pink) |

## Pen Needles

| Manufacturer Name | NDC | Product Description | Gauge/Size |
|---|---|---|---|
| Becton Dickinson & Company | 08290-3207-49 | Ultra-Fine Micro Pen Needle | 32 G X 1/4" |
| Becton Dickinson & Company | 08290-3201-19 | Ultra-Fine Mini Pen Needle | 31 G X 3/16" |
| Becton Dickinson & Company | 08290-3201-22 | Ultra-Fine Nano Pen Needle | 32 G X 5/32" |
| Becton Dickinson & Company | 08290-3282-03 | Ultra-Fine Original Pen Needle | 29 G X 1/2" |
| Becton Dickinson & Company | 08290-3201-09 | Ultra-Fine Short Pen Needle | 31 G X 5/16" |
| Becton Dickinson & Company | 08290-3205-50 | Nano 2 Gen Pen Needle | 32 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-3429-01 | Pentips | 29 G X 1/2" |
| Owen Mumford USA, Inc. | 08470-3430-01 | Pentips | 31 G X 5/16" |
| Owen Mumford USA, Inc. | 08470-3440-01 | Pentips | 32 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-3450-01 | Pentips | 31 G X 3/16" |
| Owen Mumford USA, Inc. | 08470-3490-01 | Pentips | 31 G X 1/4" |
| Owen Mumford USA, Inc. | 08470-3495-01 | Pentips | 32 G X 1/4" |
| Owen Mumford USA, Inc. | 08470-3529-01 | Unifine Pentips | 29 G X 1/2" |
| Owen Mumford USA, Inc. | 08470-3530-01 | Unifine Pentips | 31 G X 5/16" |
| Owen Mumford USA, Inc. | 08470-3540-01 | Unifine Pentips | 32 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-3550-01 | Unifine Pentips | 31 G X 3/16" |
| Owen Mumford USA, Inc. | 08470-3560-01 | Unifine Pentips | 33 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-3590-01 | Unifine Pentips | 31 G X 1/4" |
| Owen Mumford USA, Inc. | 08470-3595-01 | Unifine Pentips | 32 G X 1/4" |
| Owen Mumford USA, Inc. | 08470-3829-01 | Unifine Pentips Plus | 29 G X 1/2" |
| Owen Mumford USA, Inc. | 08470-3830-01 | Unifine Pentips Plus | 31 G X 5/16" |
| Owen Mumford USA, Inc. | 08470-3840-01 | Unifine Pentips Plus | 32 G X 5/32" |

| | | | |
|---|---|---|---|
| Owen Mumford USA, Inc. | 08470-3850-01 | Unifine Pentips Plus | 31 G X 3/16" |
| Owen Mumford USA, Inc. | 08470-3860-01 | Unifine Pentips Plus | 33 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-3890-01 | Unifine Pentips Plus | 31 G X 1/4" |
| Owen Mumford USA, Inc. | 08470-7935-01 | Unifine Safecontrol | 30 G X 5/16" |
| Owen Mumford USA, Inc. | 08470-7930-01 | Unifine Safecontrol | 31 G X 5/16" |
| Owen Mumford USA, Inc. | 08470-7940-01 | Unifine Safecontrol | 32 G X 5/32" |
| Owen Mumford USA, Inc. | 08470-7950-01 | Unifine Safecontrol | 31 G X 3/16" |
| Owen Mumford USA, Inc. | 08470-7955-01 | Unifine Safecontrol | 30 G X 3/16" |
| Owen Mumford USA, Inc. | 08470-7990-01 | Unifine Safecontrol | 31 G X 1/4" |

## Insulin Syringes

| Manufacturer Name | NDC | Product Description | Gauge/Size |
|---|---|---|---|
| Becton Dickinson & Company | 08290-3284-11 | BD syringe and needle,insulin,1mL | 30 G X 1/2" |
| Becton Dickinson & Company | 08290-3284-18 | BD syringe and needle,insulin,1mL | 31 G X 5/16" |
| Becton Dickinson & Company | 08290-3284-31 | BD syring-needl,disp,insul,0.3 mL | 30 G X 1/2" |
| Becton Dickinson & Company | 08290-3284-38 | BD syring-needl,disp,insul,0.3 mL | 31 G X 5/16" |
| Becton Dickinson & Company | 08290-3284-40 | BD syrge-ndl,ins 0.3 mL half mark | 31 G X 5/16" |
| Becton Dickinson & Company | 08290-3284-66 | BD syringe-needle,insulin,0.5 mL | 30 G X 1/2" |
| Becton Dickinson & Company | 08290-3284-68 | BD syringe-needle,insulin,0.5 mL | 31 G X 5/16" |
| Becton Dickinson & Company | 08290-3267-30 | BD syringe,insul U-500,ndl,0.5mL | 31 G X 15/64" |
| Becton Dickinson & Company | 08290-3249-09 | BD syring-needl,disp,insul,0.3 mL | 31 G X 15/64" |
| Becton Dickinson & Company | 08290-3249-10 | BD syringe-ndl,ins 0.3 mL half mark | 31 G X 15/64" |
| Becton Dickinson & Company | 08290-3249-11 | BD syringe-needle,insulin,0.5 mL | 31 G X 15/64" |
| Becton Dickinson & Company | 08290-3249-12 | BD syringe and needle,insulin,1mL | 31 G X 15/64" |
| Ultimed Inc. | 08222-0933-56 | Ulticare Ins 0.3 Ml | 30 G X 1/2" |
| Ultimed Inc. | 08222-9100-66 | Ulticare Ins 0.3 Ml | 31 G X 1/4" |
| Ultimed Inc. | 08222-9100-80 | Ulticare Ins 0.5 Ml | 31 G X 1/4" |
| Ultimed Inc. | 08222-9100-97 | Ulticare Ins 1 Ml | 31 G X 1/4" |
| Ultimed Inc. | 08222-0933-94 | Ulticare Syr 0.3 Ml | 30 G X 5/16" |
| Ultimed Inc. | 08222-0935-92 | Ulticare Syr 0.5 Ml | 30 G X 5/16" |
| Ultimed Inc. | 08222-0931-96 | Ulticare Syr 1 Ml | 30 G X 5/16" |
| Ultimed Inc. | 08222-0943-91 | Ulticare Syr 0.3 Ml | 31 G X 5/16" |
| Ultimed Inc. | 08222-0945-99 | Ulticare Syr 0.5 Ml | 31 G X 5/16" |
| Ultimed Inc. | 08222-0941-93 | Ultcare Ins Syr 1 Ml | 31 G X 5/16" |
| Ultimed Inc. | 08222-0931-58 | Ulticare Ins Syr 1 Ml | 30 G X 1/2" |
| Ultimed Inc. | 08222-0935-54 | Ulticare Ins 0.5 Ml | 30 G X 1/2" |
| Ultimed Inc. | 08222-0933-56 | Ulticare Ins 0.3 Ml | 30 G X 1/2" |
| Ultimed Inc. | 08222-0821-83 | Ulticare Ins Syr 1 Ml | 28 G X 1/2" |
| Ultimed Inc. | 08222-0923-97 | Ulticare Syrin 0.3 Ml | 29 G X 1/2" |
| Ultimed Inc. | 08222-0925-95 | Ulticare Syr 0.5 Ml | 29 G X 1/2" |
| Ultimed Inc. | 08222-0921-99 | Ulticare Ins Syr 1 Ml | 29 G X 1/2" |

## Ketone Strips

### *Quantity Limits*

- 120 strips per 30 days

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Trivida Health, Inc. | 56151-0601-01 | Ketone Test Strip |
| Trivida Health, Inc. | 56151-0601-50 | Ketone Test Strip |

## Continuous Glucose Monitors (CGM)

### Preferred CGM

### *Quantity Limits*

- NDC 08627005303- Dexcom G6 Sensor: 3 ten-day sensors/box= up to qty 9/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter: 1= 90-day supply (4 transmitters/365 days allowed)
- NDC 08627009011- Dexcom G6 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007701- Dexcom G7 Sensor: 1 ten-day sensor/box= up to qty 9/90-day supply
- NDC 08627007801- Dexcom G7 Receiver: 1= 250-day supply (1 receiver/365 days allowed)

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Dexcom, Inc. | 08627-0016-01 | Dexcom G6 Transmitter |
| Dexcom, Inc. | 08627-0053-03 | Dexcom G6 Sensor |
| Dexcom, Inc. | 08627-0091-11 | Dexcom G6 Receiver |
| Dexcom, Inc. | 08627-0077-01 | Dexcom G7 Sensor |
| Dexcom, Inc. | 08627-0078-01 | Dexcom G7 Receiver |

### Non-Preferred CGM

A coverage exception will be considered for members that has had a Medtronic Insulin pump for over a year or have had a Medtronic insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration with their insulin pumps. Please submit supporting information for the coverage of a Guardian CGM along with prior authorization information to meet the requirements as outlined in criteria below.

If the Medtronic insulin pump is older than 4 years, the authorization period will be shortened to verify that the pump is still functioning for re-authorization. If the Medtronic Insulin pump fails, the expectation is to switch to an insulin pump that is compatible with a preferred CGM.

- Guardian Sensor 3: max of 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 4: max of 1 per 365-day supply

Guardian Sensor 4 is preferred since no calibration is required. Clinical justification for use of Guardian Sensor 3 must be submitted (subject to clinical review).
Calibrating your Sensor - MiniMed™ 780G System Support | Medtronic (medtronicdiabetes.com)

Please contact Medtronic for replacement sensor and transmitters:
Sensor and Transmitter Support - Product Support | Medtronic (medtronicdiabetes.com)

### *Concurrent Medication Required*

- Please submit PA for sensor, if PA is approved, **please bill sensors first** followed by the transmitter or receiver. If the transmitter or receiver is billed first, a "prior authorization required" rejection will occur even if a sensor PA has already been approved.

### *Prior Authorization Criteria*

Continuous Glucose Monitor (CGM) Prior Authorization Form

*Initial Criteria – Approval Duration: 12 months (Until due date or 6 months, if unknown, for gestational diabetes)*

- The member must meet **one of the following** criteria (1 or 2):
  1. The member has diabetes (e.g., type 1, type 2, gestational diabetes)
  2. The member has recurrent hypoglycemia and CGM is prescribed by or in consult with, a medical geneticist or an endocrinology specialist.
- The member must not have life expectancy of less than 12 months.
- The member must not reside in a skilled nursing facility.
- Member with Type 1 or Type 2 Diabetes (not applicable if pregnant) must meet **both of the following** (1 and 2):
  1. The most recent A1c must be provided.
  2. **Both the following** must be agreed to by attestation:
     - The member will maintain regular provider visits to review glycemic control every 3-6 months.
     - CGM data will be reviewed to adjust/modify medication regimen and improve outcomes and not solely for hypoglycemia alerts.
- Members with Type 2 Diabetes (not applicable if pregnant) must meet **one of the following** criteria (1, 2, or 3):
  A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
  B. The member is currently Humulin R U-500 or an insulin pump.
  C. The member was unable to achieve goal (A1c < 7% or TIR > 70%) despite triple combination therapy consisting of long-acting insulin dose of at least 10 units per day combined with two other non-insulin antihyperglycemic agents (oral or injectable), at the maximum tolerated dose with good adherence at least 3 months, as evidenced by refill history with paid claims or pharmacy printouts.

*Renewal Criteria – Approval Duration: 12 months*
*For diagnosis of diabetes (not applicable when pregnant):*

- The most recent A1c or TIR must be submitted.
- One of the following must be met:
  - *Approval 12 months*:
    A1c and/or TIR must progress toward or be within goal (A1c < 7% or TIR > 70%) from last approval:
  - *Approval 6 months:*
    A1c and/or TIR is outside of goal and has worsened (worsened is defined as > 0.5% increase of A1c or 5% decrease in TIR) from last approval.
    One of the following must be met:
    - A member has been referred to diabetic educator or diabetic specialist for treatment plan.
    - CGM data must have been reviewed to evaluate/adjust therapy and develop a treatment plan

## Test Strip Requests after CGM approval

For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit https://www.dexcom.com/contact

- ND Medicaid will cover 200 test strips per year to facilitate instances where CGM is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule: Is my Dexcom sensor accurate?

### *Prior Authorization Criteria*

- The following criteria will apply if CGM has previously been paid, but will no longer be used and regular test strip quantities are requested:
  - The member must be seen for education by a diabetic specialist or educator
  - Documentation must be submitted noting what caused the CGM failure and education / mitigation efforts that have been taken to prevent the failure, including the following as applicable:
    - Stickiness: Skin adhesive and / or overpatches have been trialed without success
    - Sensor not working: at least 2 sensor replacements have been trialed
    - Sensitive Skin: How can I avoid irritated or sensitive skin caused by the sensor adhesive?

## CGM Supplies Coverage FAQ

**Does ND Medicaid cover Dexcom daily calibration?**
- No, the unique Dexcom sensor code must be entered that is printed on each sensor's adhesive label during the startup period, so finger sticks and calibration are not required.
- Does the Dexcom G6 Continuous Glucose Monitoring (CGM) System require calibrations?
- Can I calibrate Dexcom G7? | Dexcom

**Will test strips be covered in addition to Dexcom?**
- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule.
- Is my Dexcom sensor accurate?

**Does ND Medicaid cover additional sensors, transmitters, or receivers if mine is faulty or broken?**
- For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit https://www.dexcom.com/contact

**If my patient is currently on a CGM that is not Dexcom, is there a grandfathering period?**
- No, the member should be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that already have a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration.

**Does ND Medicaid cover Dexcom G6 for members in Long Term Care facilities?**
- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B, an override will need to be obtained for coverage.
- In all cases, the member must meet prior authorization criteria for coverage.

**How is CGM billed for Medicaid Expansion members?**
- CGM will need to be billed to ND Medicaid for Medicaid Expansion members.

**How is CGM billed for Special Health Services (SHS) members eligible for ND Medicaid?**
- Members receiving CGM other than Dexcom will need to work with SHS for CGM coverage. Exceptions will be considered for members that already have a Medtronic insulin pump to allow for CGM integration.

### *Billing FAQ*

**If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this be covered?**
- No, the code will only be covered for members with primary insurance plans that require CGM to be billed on the medical side. Members will need to be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that have had a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to

eligibility for ND Medicaid or to allow for CGM integration. Medtronic CGM must be billed on the pharmacy side.

**Will ND Medicaid cover Dexcom through medical billing?**

- ND Medicaid requires Dexcom to be billed through pharmacy NCPDP D.0 billing.
- Exceptions may be made for cases where primary insurance requires Dexcom to be billed with medical billing.

### *Other Insurance FAQ*

**If primary insurance only covers CGM other than Dexcom, will ND Medicaid pay the copay?**

- If primary insurance excludes coverage of a Dexcom, ND Medicaid may make an exception to cover a non-covered CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom, the member will need to switch to Dexcom for ND Medicaid to pay the copay.

**Does ND Medicaid cover Dexcom if member has primary insurance, but it does not cover CGM?**

- ND Medicaid may cover Dexcom as a primary payer if CGM is wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover CGM as a primary payer if a prior authorization is denied for medical necessity by the primary insurance.

**Will ND Medicaid cover Dexcom if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?**

- ND Medicaid will not cover Dexcom if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Dexcom benefit.

## Tubeless Insulin Pumps

### *Quantity limits:*

- NDC 08508200005 - Omnipod DASH Refill Pods – 10 pods per 30-day supply
- NDC 08508300001 - Omnipod 5 Intro Kit – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300021 - Omnipod 5 Refill Pods – 10 pods per 30-day supply
- NDC 08508300088 - Omnipod 5 Intro G6 for Libre 2 – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300042 - Omnipod 5 G6 Refill Pods for Libre 2 – 10 pods per 30-day supply

Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

| Manufacturer Name | NDC | Product Description |
|---|---|---|
| Insulet, Inc. | 08508-2000-05 | Omnipod DASH Refill Pods |
| Insulet, Inc. | 08508-3000-01 | Omnipod 5 Intro Kit |
| Insulet, Inc. | 08508-3000-21 | Omnipod 5 Refill Pods |
| Insulet, Inc. | 08508-3000-42 | Omnipod 5 FSL2 Plus G6 Pods |
| Insulet, Inc. | 08508-3000-88 | Omnipod 5 FSL2 Plus G6 Intro Kits |

### *Prior Authorization Criteria*

Tubeless Insulin Pump (Omnipod) Prior Authorization Form

*Initial Criteria – Approval Duration: 12 months*

- The requested medication must be prescribed by, or in consult with, an endocrinologist, diabetic educator, or prescriber specializing in the treatment of diabetes or prescriber must attest to all of the following:
  A. The member will maintain regular provider visits to review glycemic control data every 3-6 months.
  B. The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
- The member has not received a tubed insulin pump within the past 4 years or must be experiencing elevated glucose levels from disconnecting due to contact or swimming sports.
- The member must be using a compatible rapid-acting insulin.
- The member must have one of the following (A, B, or C):
  A. Diabetes type 1 or type 2
  B. Diabetes due to pancreatectomy
  C. Diabetes due to an auto-immune beta cell destruction requiring insulin therapy with a long-acting and short-acting insulin for the past 6 months, as evidenced by paid claims or pharmacy print outs.
- Members with Type 2 Diabetes must meet **one of the following** criteria (1 or 2):
  A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
  B. The member is currently Humulin R U-500 or an insulin pump.
- Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

## Omnipod Coverage FAQ

For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

**Does ND Medicaid cover insulin pens, syringes, or vials if Omnipod is discontinued?**

- Transition should be coordinated with diabetic specialist or educator.
- Current vials of rapid acting insulin should be exhausted before switching to pens. See Insulin category for a list of preferred products.
- Current supply of pods should be exhausted prior to switching to injections.

**Does ND Medicaid cover additional pods or Personal Diabetes Manager (PDM) if mine is faulty or broken?**

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

**Does ND Medicaid cover additional pods, Personal Diabetes Manager (PDM), replacement USB cords or rechargeable batteries if mine is lost or stolen?**

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.
- PDMs, USB cords, and rechargeable batteries may be replaced once every 365 days.
- Pods are not replaceable.

**Will ND Medicaid cover Omnipod through medical billing?**

- ND Medicaid requires Omnipod to be billed through pharmacy NCPDP D.0 billing.

**How is Omnipod billed for Medicaid Expansion and Special Health Services (SHS) ND Medicaid eligible members?**

- Omnipod will need to be billed to ND Medicaid for Medicaid Expansion members.
- Omnipod will need to be billed to ND Medicaid for SHS members who are eligible for ND Medicaid

**Does ND Medicaid cover Omnipod for members in Long Term Care facilities?**

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

**Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?**

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

**Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?**

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

# Appendix A: Concurrent Antipsychotics

## Concurrent Oral Antipsychotic

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

***Cross-Tapering Plans ARE covered***

Antipsychotic cross-taper plans are covered upon request. An expected plan and timeline must be included with the request.

***Use of Multiple Antipsychotics MAY be covered***

The use of two or more antipsychotics should be limited to cases where three trials of adequate dose and duration monotherapy have been failed including a trial of clozapine. Previous adequate trials with response should be well documented.

The use of one antipsychotic to target one symptom and another antipsychotic to target an additional symptom is not covered. A single antipsychotic can target multiple symptoms.

### Oral Combination Therapy Criteria

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

*Approval:* An authorization of oral combination therapy for 3 months

- One of the following must be met (1-3):
  1. The member is stabilized on regimen and is establishing care with the prescriber.
  2. The member has been discharged from a psychiatric hospital within the past month.
  3. Cross tapering from one oral antipsychotic to another.
  4. The prescriber must provide clinical justification (subject to clinical review)

*Approval:* An authorization of oral combination therapy for 12 months

- For the treatment of schizophrenia, member must meet one of the following:
  - The member has tolerated 2 monotherapy antipsychotic trials at a therapeutic dose and duration.
- For other indications:

- The prescriber must provide clinical justification that all alternative antipsychotic active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review).

*Approval:* An authorization of oral combination therapy for 2 years

- The member is using aripiprazole for hyperprolactinemia.
- The member has been stabilized on oral combination for over a year and has not had any psychiatric hospitalizations or breakthrough symptoms.
- The prescriber must provide clinical justification (subject to clinical review)

## *Special considerations*

### Aripiprazole

- Aripiprazole is supported in the compendia for use for treatment of drug-induced hyperprolactinemia, caused by antipsychotics. Therefore, upon request, aripiprazole is allowed in combination with other antipsychotics for the treatment of hyperprolactemia.

### Clozapine

- Clozapine should be reserved for treatment resistant cases where two or more monotherapy trials have already failed. In cases of clozapine treatment resistance and augmentation is considered, note that aripiprazole has been shown to be the most effective antipsychotic in combination with clozapine. Combination therapy is allowed without approval.

### Haloperidol

- Haloperidol may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

### Olanzapine

- Olanzapine may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

### Quetiapine

- Nighttime akathisia (e.g., nighttime dosing with risperidone) or daytime sedation (e.g., quetiapine ER dosed at nighttime) must prevent ability to titrate to effective dose with monotherapy.
- Other sleeping medications must be trialed. Primary use for insomnia will not be approved.

# Long-Acting Injectable and Oral Combination

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Shortened interval requests are ***not covered*** as they are not supported in the FDA dosing recommendations or compendia.

## Experiencing wearing off symptoms during the titration period (first 3 months of treatment) or first-time experiencing breakthrough symptoms:

*Approval:* A 3-month authorization of oral supplemental of the same active ingredient

- The medication requires oral overlap at initiation.
- The member has received a proper loading dose at initiation or recommended oral supplementation and is experiencing breakthrough symptoms.

## Ongoing request (> 1 incident of breakthrough symptoms after titration):

*Approval:* An authorization of oral supplemental for 12 months

- A MedWatch form for the long-acting antipsychotic must be filled out and attached to request
- The dose must be optimized to maximum FDA approved dose for the LAI antipsychotic
    - A 3-month override of the same active ingredient may be considered for breakthrough symptoms while optimizing dose
- The member must have breakthrough symptoms for 2 or more injection cycles
- One of the following (1, 2, or 3) must be met if breakthrough symptoms are occurring earlier than 75% of recommended interval:
    1. The member must have had greater than a 20% reduction in symptoms with continued improvement
    2. The member must have had greater than a 50% reduction in symptoms
    3. One of the following must be met:
        - The member has had 2 monotherapy antipsychotic trials for an adequate duration
        - The prescriber must provide justification that all alternative active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review)

# Appendix B: Antidepressant Cross Tapering:

## Selective Serotonin Reuptake Inhibitors (SSRIs) switched to:

### Selective Serotonin Reuptake Inhibitors (SSRIs)

***Cross Taper is NOT covered***

Direct switch between SSRIs is typically well-tolerated as SSRIs overlap in their mechanism of action.

### Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

***Cross Taper is generally NOT covered, case by case coverage may be provided***

Direct switch between SNRI and SSRI is typically well-tolerated because both SNRIs and SSRIs have strong serotonergic properties, with the following exceptions:

- Patient switching from high dose SSRIs, cross tapering may be of benefit
- Patient switching from fluoxetine or paroxetine to duloxetine or venlafaxine should start SNRI at a low dose. Fluoxetine and paroxetine inhibit the metabolization of duloxetine and venlafaxine.

### Tricyclic Antidepressants

***Cross Taper is covered***

Cross tapering is recommended. Tricyclic antidepressants should be started at a low dose especially when discontinuing fluoxetine, fluvoxamine, and paroxetine. These SSRIs can inhibit the metabolism of tricyclic antidepressants resulting in higher levels of tricyclic antidepressants. Tricyclic antidepressants can be fatal in overdose. Most SSRIs will clear the system within 5 days, but fluoxetine will persist for up to 5 weeks.

### Monoamine oxidase inhibitor (MAOIs)

***Cross Taper is NOT covered***

Cross tapering is not recommended and can result in serotonin syndrome or severe hypertensive crisis. A washout period of two weeks is recommended between last dose of SSRI and MAOI except in the case of fluoxetine, where a 5-week washout period is recommended.

### Other Antidepressants

***Cross Taper is covered***

## All other Antidepressants:

***Cross Taper is covered***

# Appendix C: Prior Authorization Review Dates

| Date | Category |
|---|---|
| 12/04/2024 | Stimulants for ADHD |
| 09/04/2024 | Molluscum Contagiosum |
| 09/04/2024 | Epidermolysis Bullosa |
| 09/04/2024 | Metabolic Dysfunction–Associated Steatohepatitis |
| 06/05/2024 | Acid Blockers |
| 06/05/2024 | Seborrheic Dermatitis |
| 06/05/2024 | Primary Hyperoxaluria Type 1 |
| 06/05/2024 | Myasthenia Gravis |
| 06/05/2024 | Duchenne Muscular Dystrophy |
| 06/05/2024 | Paroxysmal Nocturnal Hemoglobinuria |
| 12/06/2023 | Diuretics |
| 12/06/2023 | Menopause |
| 06/07/2023 | Hyperparathyroidism |
| 06/07/2023 | Influenza |
| 06/07/2023 | Neuromyelitis Optica Spectrum Disorder |
| 06/07/2023 | Urea Cycle Agents |
| 12/07/2022 | Prurigo Nodularis |
| 12/07/2022 | Endometriosis Pain |
| 12/07/2022 | Hematopoietic Syndrome of Acute Radiation Syndrome (Nplate) |
| 12/07/2022 | Amyloidosis |
| 12/07/2022 | Amyotrophic Lateral Sclerosis (ALS) |
| 12/07/2022 | Chelating Agents |
| 09/07/2022 | Presbyopia |
| 09/07/2022 | Hypertrophic Cardiomyopathy |
| 09/07/2022 | Cushing’s Syndrome |
| 09/07/2022 | Vernal Keratoconjunctivitis |
| 09/07/2022 | Wilson’s Disease |
| 06/01/2022 | Familial Cholestasis Pruritis |
| 03/02/2022 | Chronic Kidney Disease |
| 03/02/2022 | Lupus |
| 12/01/2021 | Atopic Dermatitis/Eczema |
| 12/01/2021 | Non-Stimulants for ADHD |
| 09/01/2021 | Heart Failure |
| 09/01/2021 | Nasal Polyps |
| 09/01/2021 | Chronic Idiopathic Urticaria |
| 09/01/2021 | Uterine Fibroids |
| 09/01/2021 | Sedative/Hypnotics – Hetlioz |
| 06/02/2021 | Sickle Cell Disease |
| 06/02/2021 | Fabry Disease |
| 06/02/2021 | Imcivree |
| 06/02/2021 | Bowel preparation agents |
| 03/03/2021 | Evrysdi |

| | |
|---|---|
| 03/03/2021 | Hereditary angioedema |
| 03/03/2021 | Irritable bowel syndrome |
| 12/02/2020 | Agents for the treatment of diabetic gastroparesis |
| 12/02/2020 | Oriahnn |
| 12/02/2020 | Dojolvi |
| 09/02/2020 | Palforzia |
| 09/02/2020 | Mytesi |
| 09/02/2020 | Antifibrinolytic agents |
| 09/02/2020 | ACL inhibitors (Nexletol, Nexlizet) |
| 09/02/2020 | Cystic fibrosis agents |
| 06/03/2020 | Conjupri |
| 03/04/2020 | Glucagon agents |
| 03/04/2020 | Ofev for treatment of scleroderma with interstitial lung disease |
| 12/04/2019 | antifungal agents for aspergillus and candidiasis infections |
| 12/04/2019 | eosinophilic asthma agents |
| 09/04/2019 | short-acting opioid analgesic agents |
| 09/04/2019 | agents for the treatment of thrombocytopenia |
| 09/04/2019 | agents for the treatment of interstitial cystitis |
| 09/04/2019 | agents for the treatment of narcolepsy |
| 06/05/2019 | Sivextro |
| 06/05/2019 | Nuzyra |
| 06/05/2019 | agents for treatment of osteoporosis |
| 06/05/2019 | agents for treatment of hyperkalemia |
| 06/05/2019 | agents for treatment of Parkinson’s disease |
| 04/09/2019 | Orilissa |
| 04/09/2019 | agents for treatment of vaginal anti-infectives |
| 04/09/2019 | agents for treatment of glaucoma |
| 04/09/2019 | agents for treatment of dry eye syndrome |
| 12/05/2018 | glyburide and Avandia |
| 12/05/2018 | Lucemyra |
| 12/05/2018 | Palynziq |
| 12/05/2018 | Roxybond |
| 12/05/2018 | Siklos |
| 09/05/2018 | Daxbia |
| 09/05/2018 | Dermatophytosis (Tinea infections) agents |
| 09/05/2018 | Migraine prophylaxis |
| 09/05/2018 | Millipred DP |
| 09/05/2018 | Rytary |
| 06/06/2018 | Anzemet and Zuplenz |
| 06/06/2018 | biosimilar agents |
| 06/06/2018 | topical corticosteroid agents |
| 06/06/2018 | Dupixent |
| 06/06/2018 | Gocovri |
| 06/06/2018 | Tussicaps |

| | |
|---|---|
| 03/07/2018 | Skelaxin |
| 03/07/2018 | Eucrisa |
| 09/06/2017 | Proglycem |
| 09/06/2017 | Biltricide |
| 03/01/2017 | prednisolone ODT, Millepred, Veripred |
| 03/01/2017 | metformin OSM |
| 03/01/2017 | testosterone oral |
| 12/07/2016 | Namenda XR |
| 12/07/2016 | Dihydroergotamine |
| 12/07/2016 | Tetracycline |
| 12/07/2016 | Spiriva Respimat 2.5 mcg |
| 12/07/2016 | ophthalmic corticosteroids |
| 12/07/2016 | erythropoiesis-stimulating agents |
| 09/07/2016 | Kits |
| 09/07/2016 | dipeptidyl peptidase-4 (DPP-4) inhibitors |
| 09/07/2016 | Immunoglobulins |
| 09/07/2016 | topical agents used to treat plaque psoriasis |
| 09/07/2016 | platelet aggregation inhibitors |
| 09/07/2016 | Antihyperuricemics |
| 06/01/2016 | Glumetza |
| 06/01/2016 | naloxone rescue medications |
| 06/01/2016 | Naltrexone |
| 06/01/2016 | Edecrin |
| 06/01/2016 | interleukin-5 antagonist monoclonal antibodies |
| 06/01/2016 | Acitretin |
| 06/01/2016 | lice medications |
| 06/01/2016 | NK1 receptor antagonists |
| 06/01/2016 | Tirosint |
| 03/02/2016 | insulins |
| 03/02/2016 | steroid inhalers |
| 03/02/2016 | digestive enzymes |
| 03/02/2016 | nasal steroids |
| 03/02/2016 | otic anti-infectives |
| 03/02/2016 | ulcer anti-infectives |
| 12/02/2015 | Marinol |
| 12/02/2015 | skin pigment products |
| 12/02/2015 | inhaled corticosteroid/LABA combination products |
| 12/02/2015 | Movantik |
| 12/02/2015 | medications used to treat irritable bowel syndrome/OIC |
| 12/02/2015 | medications used to treat ulcerative colitis |
| 12/02/2015 | SGLT2 products |
| 12/02/2015 | immediate release oxycodone |
| 12/02/2015 | inhaled anti-infectives for cystic fibrosis |
| 12/02/2015 | leukotriene modifiers |

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| 09/02/2015 | cholesterol lowering drugs |
| 09/02/2015 | injectable anticoagulants |
| 09/02/2015 | Akynzeo |
| 09/02/2015 | Nuvessa |
| 09/02/2015 | Cholbam |
| 06/03/2015 | Otezla |
| 06/03/2015 | Xtoro |
| 06/03/2015 | Hemangeol |
| 06/03/2015 | Lemtrada |
| 06/03/2015 | agents used to treat idiopathic pulmonary fibrosis |
| 06/03/2015 | GLP-1 receptor agonists |
| 06/03/2015 | topical therapies for onychomycosis |
| 12/03/2014 | testosterone products |
| 12/03/2014 | phosphate binders |
| 12/03/2014 | Zontivity |
| 12/03/2014 | Evzio |
| 09/03/2014 | Northera |
| 09/03/2014 | Oral Allergen Extracts |
| 06/02/2014 | Cathflo |
| 06/02/2014 | Intranasal Cyanocobalamin Products |
| 06/02/2014 | Luzu |
| 06/02/2014 | Noxafil |
| 06/02/2014 | Bethkis |
| 03/03/2014 | Statins |
| 03/03/2014 | Vecamyl |
| 12/03/2013 | Brisdelle |
| 12/03/2013 | Nitroglycerin Lingual Spray/Sublingual Tablets |
| 12/03/2013 | Agents Used to Treat COPD |
| 12/03/2013 | Epinephrine Auto-Injection Devices |
| 12/03/2013 | Pulmozyme |
| 09/09/2013 | Rayos |
| 09/09/2013 | Diclegis |
| 09/09/2013 | Sitavig |
| 09/09/2013 | Onmel |
| 09/09/2013 | Giazo |
| 06/03/2013 | Fulyzaq |
| 06/03/2013 | Xeljanz |
| 03/11/2013 | Genitourinary Smooth Muscle Relaxants |
| 03/11/2013 | Agents Used to Treat Multiple Sclerosis |
| 12/03/2012 | Actinic Keratosis |
| 12/03/2012 | Moxeza |
| 09/17/2012 | Kalydeco |
| 09/17/2012 | Kuvan |
| 09/17/2012 | Elaprase |

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| 06/04/2012 | Lorzone |
| 06/04/2012 | Provigil |
| 06/04/2012 | Kapvay |
| 06/04/2012 | Dexpak/Zemapak |
| 06/04/2012 | Xifaxan |
| 06/04/2012 | Vanos |
| 03/05/2012 | Pulmonary Arterial Hypertension Agents |
| 03/05/2012 | Topical Acne Agents |
| 03/05/2012 | Benign Prostatic Hyperplasia Agents |
| 03/05/2012 | Juvisync/Combination Products |
| 03/05/2012 | Gralise |
| 12/05/2011 | Dificid |
| 12/05/2011 | New Oral Anticoagulants |
| 12/05/2011 | agents used to treat Hereditary Angioedema |
| 09/12/2011 | Asacol HD |
| 09/12/2011 | Ophthalmic Antihistamines |
| 09/12/2011 | Horizant |
| 09/12/2011 | Daliresp |
| 09/12/2011 | narcotics with high dose APAP |
| 06/06/2011 | Nuedexta |
| 06/06/2011 | Nexiclon |
| 06/06/2011 | Topical ketoconazole products |
| 03/07/2011 | Statins |
| 03/07/2011 | Gilenya |
| 03/07/2011 | Xyrem |
| 12/06/2010 | agents used to treat Hepatitis C |
| 12/06/2010 | ODT preparations |
| 12/06/2010 | Oravig |
| 12/06/2010 | Zyclara |
| 12/06/2010 | Clorpres |
| 12/06/2010 | Livalo |
| 12/07/2009 | Hemophilia |
| 12/07/2009 | Sancuso |
| 12/07/2009 | Relistor |
| 12/07/2009 | Nuvigil |
| 12/07/2009 | Nucynta |
| 09/14/2009 | Uloric |
| 09/14/2009 | Moxatag |
| 09/14/2009 | Targeted Immune Modulators |
| 06/01/2009 | Aczone |
| 12/01/2008 | Triptans |
| 12/01/2008 | Vusion |
| 09/08/2008 | Chantix |
| 09/08/2008 | Carisoprodol |

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| 02/04/2008 | Ophthalmic Anti-infectives |
| 08/20/2007 | High-Cost Medications |
| 08/20/2007 | Ketek |
| 08/20/2007 | Xopenex |
| 08/20/2007 | Tekturna |
| 08/20/2007 | Synagis |
| 08/20/2007 | Amrix |
| 06/04/2007 | Qualaquin |
| 12/11/2006 | Exubera |
| 12/11/2006 | Solodyn and Oracea |
| 12/11/2006 | Oxycontin |
| 11/13/2006 | Generic medications |
| 11/13/2006 | Vigamox and Zymar |
| 11/13/2006 | Boniva |
| 05/01/2006 | Growth Hormone |
| 05/01/2006 | Sedative/Hypnotics Agents |
| 02/13/2006 | Actoplus met |
| 11/07/2005 | Revatio |
| 08/08/2005 | Zanaflex capsule |
| 12/13/2004 | ACE inhibitors |
| 12/13/2004 | ARBs |
| 12/13/2004 | Proton Pump Inhibitors |
| 01/26/2004 | COX-II and brand name NSAIDS |
| 11/03/2003 | Antihistamines |
| 04/29/2002 | Out of State Drugs |
| 09/01/1999 | Xenical |

# Appendix D: Harm Reduction Pathway

*Harm Reduction Pathway Criteria:*

The following criteria may be provided by a pharmacist (billed through the MTM program), a Syringe Service Program, or clinic-based E&M billed service (provided by a nurse or independent practitioner)

- Two visits are required prior to drug approval, a third visit during treatment is strongly recommended.

### *Persons who Inject Drugs (PWID):*

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Referral to Syringe Service Program
- Access to and use of sterile syringes, needles, and injection equipment (may not be purchased using state funds including billing Medicaid per NDCC 23-01)
- Counseling on storage and disposal of injection equipment safe and legal manner
- Education and training on drug overdose response and treatment, including access and administration of overdose reversal medication.

- Education, referral, and linkage to human immunodeficiency virus, viral hepatitis, and sexually transmitted disease prevention, treatment, and care services
- Substance Use Disorder treatment information, and referrals to treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Use of sterile syringe, needle, and injection is implemented.
- Storage and disposal of injection equipment safe and legal manner

### *People with Alcohol Use Disorder:*

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Education on the impact of alcohol to liver health (i.e., continued use can result in development of cirrhosis even in the absence of Hepatitis C)
- Counseling on how to reduce risk and severity of harmful consequences arising from severe alcohol intoxication (e.g., transportation services, condom use, avoiding fighting, drinking low alcohol beverages, padding furniture and stairs)
- Counseling on Safer-use Strategies: Alcohol
- Provide alcohol addiction treatment information and linkage to alcohol treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Safer-use and risk reduction strategies implemented.

**References:**

- Medical Pharmacy Billing Manual