Pharmacy Coverage Policy Manual

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Be Legendary.

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/

Preferred Drug List (PDL)

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
clobetasol 0.05% eye drops	PA	ophthalmic corticosteroids
Crexont	PA	Parkinsons's Agents / Preferred Dosage Forms
Ebglyss	PA	Atopic Dermatitis
Iqirvo	PA	Medications > $3000
Neffy	PA	Epinephrine
Nemluvio	PA	Prurigo Nodularis
Tyenne	PA	Cytokine Modulators
Yorvipath	PA	Secondary Hypoparathyroidism

Version Changes

Category	Change
Antipsychotics	Cobenfy added
Axial Spondyloarthritis/Ankylosing Spondylitis	Bimzelx added; criteria updated
Chronic Kidney Disease	Fabhalta added
Continuous Glucose Monitors (CGM)	Medtronic CGM coverage exception information added
COPD / Asthma	Tobacco cessation counseling requirement added
COPD / Asthma	Biologics criteria updated
COPD / Asthma	Specialist requirement added to Ohtuvayre
Eczema / Atopic Dermatitis	Eblyss added; criteria updated
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	Fasenra added; criteria updated
Hypothyroidism	Category Added - removed levothyroxine from preferred dosage forms
Immune Globulins	Preferred products updated
Juvenile Idiopathic Arthritis – Polyarticular Course	Cimzia added
Prurigo Nodularis	Nemluvio added; criteria updated
Secondary Hyperparathyroidism	Yorvipath added; criteria updated
Sickle Cell Disease	Oxbryta removed; criteria updated for Cell-based Gene Therapy
Ulcerative Colitis	Tremfya added

General Policies

Dispense as Written (DAW1)

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

<u>Initial Criteria - Approval Duration:</u> 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 is 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, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

CLINICAL PA REQUIRED
ABECMA (idecabtagene vicleucel) – *Medical Billing Only*
ACTHAR (corticotropin) SELF-INJECTOR
BLINCYTO (blinatumomab) – *Medical Billing Only*
BREYANZI (lisocabtagene maraleucel) – *Medical Billing Only*
CARVYKTI (ciltacabtagene autoleucel) – *Medical Billing Only*
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-gqgk) – *Medical Billing Only*
DAYBUE (trofinetide)
DOJOVI (triheptanoin)
EPKINLY (epcoritamab-bysp) – *Medical Billing Only*
FIRDAPSE (amifampridine)
FUROSCIX (furosemide)
FUROSCIX (furosemide) – *Medical Billing Only*
FYARRO (sirolimus protein-bound particles) – *Medical Billing Only*
GATTEX (teduglutide)
INCRELEX (mecasermin)
IQIRVO (elafibranor)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – *Medical Billing Only*
KYMRIAH (tisagenlecleucel) – *Medical Billing Only*
LIVDELZI (seldelpar lysine)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OCALIVA (obeticholic acid)
OXERVATE (cenegermin-bkbj)
PYRUKYND (mitapivat)
REZUROCK (belumosudil)
SKYCLARYS (omaveloxolone)
SPEVIGO (spesolimab-sbzo)
SOHONOS (palovarotene)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – *Medical Billing Only*
TECVAYLI (Inj teclistamab cqyv 0.5 mg) – *Medical Billing Only*
TIVDAK (tisotumab vedotin-tftv) – *Medical Billing Only*
VIJOICE (alpelisib)
VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing Only*
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – *Medical Billing Only*
XOLREMDI (mavorixafor)
YESCARTA (axicabtagene ciloleucel) – *Medical Billing Only*
ZOKINVY (lonafamib)
ZYNLONTA (loncastuximab tesirine-lpyl) – *Medical Billing Only*

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 Only*

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:
    A. Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
    B. 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 Only*

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	

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.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year.
- 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 1 preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria - Approval Duration: 12 months

- Documentation must be provided including that the member has achieved 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

Tocilizumab

CLINICAL PA REQUIRED
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

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)
RIABNI (rituximab-arrx) – *Medical Billing Only*	
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

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 Only*

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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*	

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:
- History of urticaria, angioedemia, or wheeze
- 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)
- 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 Only*

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
- 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*

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:
  A. colchicine
  B. NSAIDs
  C. 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)
6-mercaptopurine (6-MP)	AZASAN (azathioprine)
allopurinol 100 mg, 300 mg tablet	allopurinol 200 mg tablet
azathioprine 50 mg	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 Only*

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:
  A. allopurinol
  B. febuxostat
  C. 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) – *Medical Billing Only*
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) – *Medical Billing Only*

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.
    A. Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.
    B. 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):
    A. 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)
    B. 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)
    C. 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 Only*	

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 Only*	ALYGLO (human immunoglobulin G - stwk) – *Medical Billing Only*
GAMMAGARD S-D (human immunoglobulin G)	ASCENIV (human immune globulin G- slra)
GAMMAPLEX (human immunoglobulin G)	ASCENIV (human immune globulin G- slra) – *Medical Billing Only*
GAMMAPLEX (human immunoglobulin G) – *Medical Billing Only*	PANZYGA (human immune globulin G- ifas)
OCTAGAM (human immunoglobulin G)	PANZYGA (human immune globulin G - ifas) – *Medical Billing Only*
OCTAGAM (human immunoglobulin G) – *Medical Billing Only*	
PRIVIGEN (human immunoglobulin G)	
PRIVIGEN (human immunoglobulin G) – *Medical Billing Only*	

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 Only*	
GAMUNEX-C (human immunoglobulin gamma)	
GAMUNEX-C (human immunoglobulin gamma) – *Medical Billing Only*	

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 Only*	CUVITRU (human immunoglobulin gamma) – *Medical Billing Only*
HIZENTRA (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)

HIZENTRA (human immunoglobulin gamma) – *Medical Billing Only*	HYQVIA (human immune globulin G and hyaluronidase) – *Medical Billing Only*
XEMBIFY (immune globulin,gamma(IgG)klhw)	
XEMBIFY (immune globulin,gamma(IgG)klhw) – *Medical Billing Only*	

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
  A. 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	

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: 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 an 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
CAROSPIR (spironolactone) SUSPENSION – *Brand Required*	INSPRA (eplerenone)
eplerenone	spironolactone suspension
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	tolvaptan
ENTRESTO (sacubitril/valsartan)	
FARXIGA (dapagliflozin) – *Brand Required*	
JARDIANCE (empagliflozin)	

Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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.
  - 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)
PRALUENT PEN (alirocumab)	
REPATHA PUSHTRONEX (evolocumab)	
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

- 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.

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

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	ALTROPREV (lovastatin)
CADUET (amlodipine/atorvastatin) – *Brand Required*	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.
- 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.

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 Only*

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.
- Documentation of one of the following must be provided:

- 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
  - Nexlizet 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 Only*

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:
  - Praluent combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Nexlizet 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
- Documentation of 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	AMZEEQ (minocycline) foam
doxycycline hyclate tablet 20 mg, 100 mg	demeclocycline
doxycycline monohydrate 25 mg/5 mL suspension	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
minocycline capsule	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
tetracycline	doxycycline monohydrate tablet 150 mg
	doxycycline hyclate tablet DR
	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE
	SOLODYN ER (minocycline) TABLET
	XIMINO (minocycline) CAPSULE ER

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)
EXTINA (ketoconazole) FOAM – *Brand Required*	KETODAN (ketoconazole) FOAM
	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
	KERYDIN (tavaborole) 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 Forms Criteria – Use enough 50 mg to make correct dosage

Topical

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 the Preferred Drug List of 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) PEN

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.

Ebglyss Only:
- The member must have had a 3-month trial with Adbry, as evidenced by paid claims or pharmacy printouts

Zoryve Only:
- The member must have had a 28-day trial with Eucrisa, as evidenced by paid claims or pharmacy printouts

Epidermolysis Bullosa

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

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).
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.

- Documentation of the baseline symptoms (e.g., extensive skin blistering, number and size of wounds) that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Hidradenitis Suppurativa

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Interleukin (IL) – 17 Inhibitors

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

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 and Simponi Aria Only: The member must have failed a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Other agents: See Preferred Dosage Form criteria

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

- The member must have failed a 6-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.
- Hemangeol Only:
  - The member must have failed a 6-month trial of timolol gel forming solution, as evidenced by paid claims or pharmacy printouts.

Molluscum Contagiosum

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

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)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Interleukin (IL)-17A Inhibitor

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

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 Only*
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

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 a TNF Inhibitor 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

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.
- Stelara, Tremfya, and Wezlana 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 Siliq, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra 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).

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 have failed a 3-month trial of adalimumab, 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).

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
  A. Location of application: palms, soles, or psoriatic crusts
  B. Indication: psoriasis
  C. 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%	HALOG (halcinonide) SOLUTION	0.10%
	fluocinonide solution	0.05%		

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			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.

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 Only*
	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*	testosterone 2% (10mg/0.5g) gel MD PMP bottle
FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP – *Brand Required*	VOGELXO (testosterone) GEL PMP
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 Only*	

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.
- 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 Only*

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:
  A. Glutamic acid decarboxylase 65 (GAD) autoantibodies
  B. Insulin autoantibody (IAA)
  C. Insulinoma-associated antigen 2 autoantibody (IA-2A)
  D. Zinc transporter 8 autoantibody (ZnT8A)
  E. 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
	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.
    - 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.
- 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) *- 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:
    - 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).
- Step 2:
    - 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).
    - One of the following have been met:
        - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
        - 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, 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.

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

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

- 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).
- One of the following have been met:
    - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
    - 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, 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.

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) with relevant medical documentation attached to the request, 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
GLUCAGEN (glucagon) HYPOKIT – *Brand Required*	glucagon kit
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	GVOKE (glucagon) INJECTION

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) *–Kwikpen: Brand Co-Preferred*	ADMELOG (insulin lispro)
HUMALOG U-100 (insulin lispro) JUNIOR KWIKPEN *– Brand Co-Preferred*	HUMALOG U-200 (insulin lispro)
HUMALOG U-100 (insulin lispro) TEMPO PEN	insulin lispro vial

insulin lispro U-100 junior syringe	LYUMJEV U-100 (insulin lispro-aabc)
insulin lispro U-100 insulin pen	LYUMJEV U-200 (insulin lispro-aabc)
	LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc)

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 Humalog 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 Humalog, as evidenced by paid claims or pharmacy printouts.

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:
  - Humalog
  - 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:
  - Humalog and 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 and Levemir 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 or Levemir (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) *– Brand Required*	BASAGLAR KWIKPEN U-100 (insulin glargine)
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day *– Brand Required*	BASAGLAR TEMPO PEN U-100 (insulin glargine)
	insulin glargine U-100 (generic Toujeo)
	insulin glargine-yfgn U-100 (generic Semglee)
	REZVOGLAR U-100 (insulin glargine-aglr)
	SEMGLEE U-100 (insulin glargine) YFGN

Insulin Degludec

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

Quantity Override Request

- Toujeo Solostar 300 unit/mL, Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  - 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
  - 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).
  - 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.
- Biosimilar Agents: See Preferred Dosage Form criteria

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)
	STEGLATROMET (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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
NUTROPIN AQ NUSPIN (somatropin)	GENOTROPIN MINIQUICK (somatropin)
	HUMATROPE (somatropin)
	NGENLA (somatrogon-ghla)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (lonapegsomatropin-tcgd)
	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):
  - 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.

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

- 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.

Prader-Willi Syndrome (PWS)

See covered medications for weight loss

- The member must not have severe obesity (class 2) defined as ≥ 120% of the 95th percentile for age and gender
- If the member has obesity ≥ 95th percentile and < 120% of the 95th 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%

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial of 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 preferred agents (subject to clinical review).

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 ≥ 95th percentile and < 120% of the 95th 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.
- Documentation of 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 > 95th 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, as evidenced by medical documentation (e.g., chart notes) attached to the request:
  - 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
- 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

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 hypoparathyroidsm as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent:
    - Symptomatic hypocalcemia
    - Hyperphosphatemia
    - Renal insufficiency
    - 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 Only*	SUPPRELIN LA (histrelin) – *Medical Billing Only*
LUPRON PED DEPOT (leuprolide) – *Medical Billing Only*	
SYNAREL (nafarelin) – *Medical Billing Only*	
TRIPTODUR (triptorelin) – *Medical Billing Only*	

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 Only*

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)
- The provider must submit documentation of each of the following:
  - Thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
  - Must have a Clinical Activity Score of greater than or equal to 4
- The member has had a one-month trial of a maximally tolerated indicated dose of systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.
- The member does not have any of the following:
  - A decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
  - Corneal decompensation that is unresponsive to medical management
  - Poorly controlled diabetes or diabetes must be maximally treated by, or in consult with, an endocrinologist with good adherence.

X-linked Hypophosphatemia (XLH) or Tumor-Induced Osteomalacia

CLINICAL PA REQUIRED
CRYSVITA (burosumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (one-time 6-month approval for adult with planned orthopedic surgical

- Documentation to confirm the diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX-gene) mutation
  - Increased (FGF23) level based on laboratory reference range with unresectable phosphaturic mesenchymal tumor
- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- Documentation must be submitted confirming the member is experiencing the following:
  - Phosphate manifestations *(must have one)*
    - Fasting serum phosphate is below provided age adjusted reference range.
    - Low tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR) based on age
  - Bone manifestations *(must have one)*
    - Epiphyseal plate has not fused
    - Bone fractures

- Planned orthopedic surgical procedure

Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted demonstrating that the member has demonstrated a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Normalization of phosphate levels as defined by laboratory
  - Decrease in serum alkaline phosphatase activity
  - Improvement of renal phosphate wasting
  - Normalization of growth velocity
  - Reduction or healing of fractures
  - Improvement of Thacher Rickets Severity Score (TRSS)

Weight Loss

Antipsychotic Induced Weight Gain

- Metformin is covered without prior authorization.
- Victoza is covered without prior authorization by submitting diagnosis code T43.505A

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):
  - A. The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following:
    - Omeprazole twice daily
    - Rabeprazole or esomeprazole daily.
  - B. The member has severe esophagitis (LA Grade C/D disease)
  - C. 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 Only*

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 (i.e., acute intermittent porphyria (AIP), variegate porphyria (VP), hereditary coproporphyria (HCP), delta-aminolevulinic acid dehydratase deficient porphyria (ADP)) with the following as defined by laboratory reference range (evidenced with submitted documentation):
  - Elevated urine porphobilinogen (PBG)
  - Increased aminolevulinic acid (ALA)
  - Genetic testing confirming a mutation
- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, smoking, stress)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration (number of attacks and days of hemin are documented)

- The member has not had a liver transplant.

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 urinary ALA

Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLENPIQ	PEG 3350/SOD SUL/NACL/KCL/ASB/C
GAVILYTE-C	PLENVU
GAVILYTE-G	SUFLAVE
GAVILYTE-N	SUTAB
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	
SUPREP – *Brand Co-Preferred*	

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, antihistamines
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2).*
    - The member has had a 6-month trial with Livmarli.
  - 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 Only*	
VOWST (fecal microbiota spores, live-brpk) CAPSULE	

Monoclonal Antibody

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

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 Only*

++ 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) – *Medical Billing Only*

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)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – *IV Induction Medical Billing Only*
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) – *IV Induction Medical Billing Only*

Interleukin (IL)-23p19 Inhibitor

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

	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) *– IV Induction Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	ZYMFENTRA (infliximab-dyyb)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

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:

Stelara and Wezlana Only:

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

Tysabri Only:

- The requested medication must be prescribed by, or in consult with, an gastroenterologist

Non-Preferred Biosimilars Only:

- See Preferred Dosage Form 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)	

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:
  a. 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:
  a. 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

a. 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 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)

Prior Authorization Criteria

Prior Authorization Form – Eosinophilic Esophagitis

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed a 3-month trial of a swallowed inhaled respiratory corticosteroid (budesonide or fluticasone).

Renewal Criteria – Approval Duration: 12 months

- 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 Only*

Interleukin (IL)-23p19 Inhibitor

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

Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – *IV Induction Medical Billing Only*
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) – *IV Induction Medical Billing Only*

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TREMFYA (guselkumab) – *Medical Billing Only*
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)

	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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.
- Biosimilars Only: See Preferred Dosage Form criteria
- Entyvio Only: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Skyrizi and Tremfya Only: The member must have failed a 3-month trial of a TNF inhibitor and Entyvio, as evidenced by paid claims or pharmacy printouts.
- Omvoh, Stelara, and Wezlana Only: The member must have failed a 3-month trial of a TNF inhibitor, Entyvio, and Skyrizi, 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 – *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 Only*	

Transhyretin-directed small interfering RNA (siRNA)

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

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.
- Documentation of genetic testing confirming a pathogenic TTR mutation (e.g., V30M) must be provided.
- Documentation of one of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline Coutinho staging system stage 1 or 2
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (amyloid deposition in biopsy specimens, TTR protein variants in serum, weakness, sensory loss, decreased motor strength, decreased gait speed, etc.)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen, eplontersen).

Renewal Criteria – Approval Duration: 12 months
- Documentation of 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

TTR Stabilizers

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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 member must have wild-type TTR mediated amyloidosis or documentation of genetic confirmation of hereditary TTR mediated amyloidosis as evidenced by a pathogenic TTR mutation (e.g., V30M)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- The member has clinical signs and symptoms of the disease (heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Impaired renal function (i.e., GFR < 25)
  - Previous heart or liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be between 3 and 8 years of age.
- 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.
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 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.
- Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy.
- 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, as evidenced by medical documentation attached to the request.
- 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)

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FABRAZYME (agalsidase beta) *– Medical Billing Only*	ELFABRIO (pegunigalsidase alfa) *– Medical Billing Only*

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 (as evidenced with submitted documentation):
  - In males assigned at birth:
    - Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    - Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth and males assigned at birth with α-Gal A enzyme activity > 35 percent:
    - Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
    - Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy
    - The member is experiencing one of the following symptoms:
      - Acroparesthesias (burning pain in the extremities)
      - Angiokeratomas (cutaneous vascular lesions)
      - Hypo- or anhidrosis (diminished perspiration)
      - Corneal and lenticular opacities
      - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
      - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

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
- 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 must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Gaucher's Disease

Enzyme Replacement Therapy

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

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 (as evidenced with submitted documentation):
  - Deficiency in beta-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 (as evidenced with submitted documentation):
  - Anemia with hemoglobin less than or equal to the laboratory reported low for patient age and gender
  - Thrombocytopenia with platelet count less than 100,000/mm^3
  - Bone disease (T-score below -1.0 [DXA], height SDS <-2.25 with decreased growth velocity, bone crisis)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) 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
- Documentation has been submitted that member has experienced a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - 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 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 Only*

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.
- Documentation 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

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 medical documentation (e.g., chart notes) attached to the request (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.

Alpha-Mannosidosis

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

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)
- Documentation 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 specialist in lysosomal storage diseases
- Documentation of 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 6 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) for 4 years of age and older
    - 2-minute walk test (2-MWT) for under 4 years of age
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced in medical documentation (e.g., chart notes) attached to the request (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 for 4 years of age and older
    - 2-MWT for under 4 years of age
    - 3-minute stair climb test
    - FVC via Pulmonary Function Test

Mucopolysaccharidosis I (MPS I)

CLINICAL PA REQUIRED
ALDURAZYME (laronidase) – *Medical Billing Only*

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 expert in lysosomal storage diseases.
- Documentation 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
- Documentation of 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

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 medical documentation (e.g., chart notes) attached to the request (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 Only*

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)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity 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
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- The member does not have severe cognitive or neurologic impairment (e.g., inability to swallow)
- Documentation of one of the following must be submitted:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 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

- Documentation must be submitted confirming improvement of one of the following:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test relative improvement of 10% over baseline
  - 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 Only*

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)
- Documentation 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 is experiencing musculoskeletal signs and symptoms of MSP-IVA such as knee deformity, kyphosis, hip dysplasia, arthralgia, etc.
- Documentation of 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*

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)
- Documentation 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.
- Documentation of 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 meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*

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)
- Documentation 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.
- One or more of the following documentations must be submitted:
  - Skeletal abnormalities
  - 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
  - Liver and/or spleen volume
  - 6-minute walk test (6MWT)
  - Motor function test (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Stability or improvement in skeletal abnormalities shown on x-ray, short stature, macrocephaly
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Reduction in liver and/or spleen volume
  - Stability or improvement in 6-minute walk test (6MWT)
  - Stability or 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 (documentation must be attached).
- 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

CLINICAL PA REQUIRED
LUMIZYME (alglucosidase alpha) – *Medical Billing Only*
NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing Only*

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)
- Documentation 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 permanent invasive ventilation.
- Documentation must be submitted of the member's current motor function such as motor function, respiratory function, cardiac involvement (infantile onset) and 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)
  G. Forced Vital Capacity (FVC) via Pulmonary Function Test

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 medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including stabilization or improvement of the following:
  - Motor function, respiratory function, cardiac involvement (infantile onset)
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores
  - Forced Vital Capacity (FVC) via Pulmonary Function Test (ages 5 and older)

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)
carglumic acid	CARBAGLU (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

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

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 have a diagnosis of anemia due to beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm with ring sideroblasts.
- Documentation must be submitted of a pretreatment hemoglobin of less than 11 g/dL.
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Deep vein thrombosis or stroke within the past 24 weeks
  - Platelet count greater than 1000 x 109 per liter

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:
- Documentation must be submitted that the member requires 2 or more RBC units over an 8-week period as evidenced by the following:
  - One of the following:
    - Ring sideroblasts greater than or equal to 15%
    - Ring sideroblasts greater than or equal to 5% and less than 15% with an SF3B1 mutation
  - One of the following:
    - Serum erythropoietin greater than 500 mU/mL
    - Serum erythropoietin less than or equal to 500 mU/mL with inadequate response after a 3-month trial with a combination of an ESA (e.g., epoetin alfa) and granulocyte-colony stimulating factor (G-CSF)
  - Member has very low to intermediate risk disease defined as one of the following:

- Revised International Prognostic Scoring System (IPSS-R); very low, low, or intermediate (Score of 0 to 4.5);
- IPSS: low/intermediate-1 (Score 0 to 1)
- WHO-Based Prognostic Scoring System (WPSS): WPSS: very low, low, or intermediate (Score 0 to 2)

For anemia due to beta thalassemia:
- No prior gene therapy
- No prior HSCT
- Documentation must be submitted confirming the following:
  - 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) 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
- The member continues to have pretreatment hemoglobin of less than 11 g/dL.
- Dose will be increased to 1.25 mg/kg daily.

Cell-based Gene Therapy

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

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
- 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.
- Member must not have any of the following:
  - Prior receipt of gene therapy
  - Prior HSCT
  - 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 Only*	DESFERAL (deferoxamine) MESYLATE VIAL – *Medical Billing Only*
	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)
RIABNI (rituximab-arrx) – *Medical Billing Only*	
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Anti-Complement Therapy

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

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

- Documentation must be submitted that the member has had a beneficial 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

Tocilizumab

CLINICAL PA REQUIRED
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

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 Only*

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.
- Documentation must be submitted confirming the diagnosis, 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 Prophylaxis

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)	

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 Prophylaxis

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)	

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 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 2 x 10^13 genome copies (gc) per 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 must be negative for Factor IX inhibitor titers within the previous 30 days.

Hematopoietic, Colony Stimulating Factors

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
NIVESTYM (filgrastim-aafi)	ZARXIO (filgrastim-sndz)
RELEUKO (filgrastim-ayow)	

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	
NEULASTA ONPRO (pegfilgrastim)	
NYVEPRIA (pegfilgrastrim–apgf)	
STIMUFEND (pegfilgrastim-fpgk)	
UDENYCA (pegfligrastim-cbqv)	
UDENYCA ONBODY (pegfligrastim-cbqv)	
ZIEXTENZO (pegfilgrastim-bmez)	

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	

Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)

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)
AKYNZEO (netupitant/palonosetron) CAPSULE	aprepitant capsule
EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK – *Brand Required*	aprepitant tripack
	EMEND (aprepitant) 80 MG CAPSULES
	EMEND (aprepitant) SUSPENSION

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron) CAPSULE	SANCUSO (granisetron) PATCH
granisetron tablet	ZOFRAN (ondansetron)
	SUSTOL (granisetron) SYRINGE

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 Only*
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*

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):
  A. The member has had at least 1 transfusion in the past 6 months
  B. 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):
  A. The member has had at least 1 transfusion in the past 6 months
  B. 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.

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:
  - 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 Only*

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

- Documentation of the diagnosis must be submitted, as evidenced by the following:
  A. 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.)*
  B. Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  C. 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following:
  A. The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  B. 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)
+ADAKVEO (crizanlizumab-tmca) *– Medical Billing Only*	L-glutamine
ENDARI (glutamine) *– Brand Required*	

+ 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 must have had a 30-day trial of a 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 has experienced at least one sickle cell-related VOC within past 12 months while adherent with hydroxyurea (documentation required).
- Siklos Only:
  A. Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  B. 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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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

Cell-based Gene Therapy

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

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.
- Documentation of 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
- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

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 (documentation must include name and scheduled date of procedure)
- Documentation must include the date therapy will be initiated and discontinued:
  - 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

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)
- 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, cyclosporine)

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

Hepatology

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REZDIFFRA (resmetirom)

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, 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.
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization or improvement of fibrosis and steatohepatitis, as determined by one of the following (1-4):
  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)

Infectious Disease

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 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 are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Aspergillus and Candidiasis Infections Only:

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis

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 Only*	
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 ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI 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 ddI 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	darunavir
EVOTAZ (atazanavir/cobicistat)	NORVIR (ritonavir)
NORVIR (ritonavir) POWDER PACKET	REYATAZ (atazanavir)

PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir) – *Brand Required*	
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.
- Saqinavir – 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 Only*	
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: Jump to Criteria

Loss of Appetite

Dronabinol: Jump to Criteria

Wasting Cachexia

Serostim: Jump to Criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200 mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
SOVALDI (sofosbuvir) 200 MG TABLET	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
	ledipasvir/sofosbuvir 90mg/400mg tablet
	MAVYRET (glecaprevir/pibrentasvir)
	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	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:

- Epclusa pellet packs: Members that weigh 30 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria.
- Mavyret pellet packs: Members that weigh 45 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria.

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):
  A. 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
  B. 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. 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.

	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

- 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 Only*

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) Midwest Region RSV Regional Trends – NREVSS | CDC

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 Only*
ULTOMIRIS (ravulizumab-cwvz)
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*

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 (as evidenced by submitted documentation):
  - 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 meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 Only*

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
INVOKANA (canagliflozin)	
JARDIANCE (empagliflozin)	

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:
  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, Filspari and 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 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
  - prednisone or methylprednisolone

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.

<u>Renewal Criteria – Approval Duration:</u> 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 <1 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)
JESDUVROQ (daprodustat)
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 (CLINICAL 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 documentation from 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:
    - 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, as evidenced by lab documentation submitted with the request.

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 Only*
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)
- The member has not received a liver transplant
- Documentation of the 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)
RIABNI (rituximab-arrx) – *Medical Billing Only*	
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – *Medical Billing Only*	

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 provider must submit documentation showing that the member has experienced clinical benefit since starting treatment, as evidenced by documentation of 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)
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	FOSRENOL (lanthanum) POWDER PACK
RENVELA (sevelamer carbonate) POWDER PACK – *Brand Required*	lanthanum chew tab
	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 Forms 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)
	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).
  A. 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
LEQEMBI (lecanemab-irmb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 year
Leqembi Only:

- 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.

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	EXSERVAN (riluzole) FILM	RILUTEK (riluzole) TABLET
	QALSODY (tofersen) + *– Medical Billing Only*	
	RADICAVA (edaravone) *– Medical Billing Only*	
	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
  - Documentation of 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 chewable tablet	carbamazepine ER capsule
carbamazepine oral suspension	carbamazepine XR tablet
carbamazepine tablet	EPITOL (carbamazepine)
CARBATROL (carbamazepine) – *Brand Required*	TEGRETOL (carbamazepine oral suspension)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine)
TEGRETOL XR (carbamazepine) – *Brand Required*	

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.
  A. Diacomit is FDA approved to be used in combination with clobazam.

Quantity Limit Override

- Gabapentin: 1800 mg max dose per day

Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 1800 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)
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	DEPAKENE (valproic acid) CAPSULE
divalproex sodium ER	DEPAKENE (valproic acid) ORAL SOLUTION
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	
valproic acid oral solution	

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)
	SPRITAM (levetiracetam) SUSPENSION

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Co-Preferred*	
BANZEL (rufinamide) TABLET – *Brand Co-Preferred*	
rufinamide suspension	
rufinamide tablet	

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	topiramate ER sprinkle cap
topiramate tablet	
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, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing Only*	

Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing Only*	VYONDYS 53 (golodirsen) – *Medical Billing Only*

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.

- 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.

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

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

- 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:
  A. 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.
  B. 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
  - 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

- Provider must submit documentation of symptom improvement, as evidenced by documentation of 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

- Lumryz, Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

Migraine

Prophylaxis of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm) INJECTION	AIMOVIG (erenumab-aooe) INJECTION
EMGALITY (galcanazumab-gnlm) INJECTION	NURTEC ODT (rimegepant) TABLETS
	QULIPTA (atogepant) TABLETS
	VYEPTI (eptinezumab-jjmr) – *Medical Billing Only*

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

Non-Preferred Agents Criteria:

- The member must have failed a 3-month trial of two self-administered CGRPs (Ajovy and Emgality), as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
  - The member must have failed a 3-month trial of 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.

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

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 (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ZOMIG (zolmitriptan) NASAL SPRAY *– Brand Required*	sumatriptan spray	TOSYMRA (sumatriptan) NASAL SPRAY
		zolmitriptan spray

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) 6 MG/0.5 ML CARTRIDGE *– Brand Required*	IMITREX (sumatriptan) 4 MG/0.5 ML CARTRIDGE
IMITREX (sumatriptan) 6 MG/0.5 ML PEN INJECTOR *– Brand Required*	IMITREX (sumatriptan) 4 MG/0.5 ML PEN INJECTOR
	sumatriptan cartridge
	sumatriptan pen injector
	sumatriptan vial
	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must be unable to take oral medications (subject to clinical review).

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.

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)
RIABNI (rituximab-arrx) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	

RYSTIGGO (rozanolixizumab-noli) – *Medical Billing Only*	
VYVGART (ergartigimod alfa) – *Medical Billing Only*	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing Only*	
ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) – *Medical Billing Only*
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

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)
- 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:
    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.

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 Only*	TYSABRI (natalizumab) *– Medical Billing Only*	MAVENCLAD (cladribine)
KESIMPTA (ofatumumab)		LEMTRADA (alemtuzumab) *– Medical Billing Only*
OCREVUS (ocrelizumab) *– Medical Billing Only*		

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 Only*
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*	
UPLIZNA (inebilizumab) – *Medical Billing Only*	

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, as evidenced by medical documentation (e.g., chart notes) attached to the request (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 – Adenosine Receptor Agonist

CLINICAL PA REQUIRED
NOURIANZ (Istradefylline)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- Documentation must be provided describing deterioration in quality of response to levodopa/carbidopa therapy, including currently experiencing intermittent hypomobility, or "off" episodes (number and frequency)
- The member must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

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 – Dopamine Precursor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone 25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg	carbidopa-levodopa-entacapone 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 – Dopaminergic Agents for Intermittent Treatment of Off Episode

Subcutaneous

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – *Brand Required*	apomorphine

Enteral Suspension

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUOPA (levodopa/carbidopa)	

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
- Documentation must be provided of intermittent hypomobility or off episodes (number and frequency)
- 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)

Parkinson's Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)
cabergoline	

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

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of selegiline, as evidenced by paid claims or pharmacy printouts
- Xadago Only:
  - The requested medication must be prescribed by, or in consult with, a psychiatrist or neurologist
  - The member must be currently experiencing intermittent hypomobility or "off" episodes
  - The member must be currently taking an extended-release formulation of carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
  - The member must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes
  - The member must have failed a 30-day trial of rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

Parkinson's Agents – Non-ergot Dopamine Receptor Agonists Maintenance

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's Agents – Other

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

Spinal Muscular Atrophy (SMA)

SMN2 Gene Splicing Modifiers

CLINICAL PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – *Medical Billing Only*

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

- Spinraza Only: The member must not have severe contractures or severe scoliosis

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 documentation of 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 Only*

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 Documentation has been provided confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- 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 dopamine receptor blocking agent (DRBA).
- 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
- Documentation must be submitted of 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 *– 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

- Documentation must be submitted of 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	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLINDESSE (clindamycin) CREAM
clindamycin cream	VANDAZOLE (metronidazole) GEL
metronidazole gel	XACIATO (clindamycin phosphate) GEL
NUVESSA (metronidazole) GEL	

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
SOLOSEC (secnidazole) GRANULE PACKET	VIVJOA (oteseconazole) CAPSULES
tinidazole tablet	

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
  - 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	ALOCRIL (nedocromil)
BEPREVE (bepotastine) – *Brand Required*	ALOMIDE (lodoxamide)
cromolyn	bepotastine
olopatadine 0.1%	epinastine
PAZEO (olopatadine)	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	CILOXAN (ciprofloxacin) DROPS
gentamicin sulfate drops	gatifloxacin drops
moxifloxacin drops (generic Vigamox)	moxifloxacin drops (generic Moxeza)
neomycin SU/polymyxin B/gramicidin drops	NATACYN (natamycin) DROPS
ofloxacin drops	OCUFLOX (ofloxacin) DROPS
polymyxin B/trimethoprim drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
sulfacetamide drops	VIGAMOX (moxifloxacin) DROPS
tobramycin drops	
ZYMAXID (gatifloxacin) DROPS – *Brand Required*	

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
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
neomycin SU/bacitracin/polymyxin B 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	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
TOBRADEX (tobramycin/dexamethasone) OINTMENT	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
	NEO-POLYCIN HC (neomycin SU/bacitracin/ polymyxin B/hydrocortisone) 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
FLAREX (fluorometholone) DROPS	dexamethasone sodium phosphate drops
fluorometholone drops	difluprednate drops
FML FORTE (fluorometholone) DROPS	DUREZOL (difluprednate) DROPS
LOTEMAX (loteprednol) DROPS – *Brand Required*	EYSUVIS (loteprednol) DROPS
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	INVELTYS (loteprednol) DROPS
MAXIDEX (dexamethasone) DROPS	FML (fluorometholone) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	LOTEMAX SM (loteprednol) DROPS

prednisolone acetate 1% drops	loteprednol eye drops
prednisolone sodium phosphate 1% drops	loteprednol gel eye drops
	PRED FORTE 1% (prednisolone acetate) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
diclofenac sodium drops	ACULAR LS (ketorolac) DROPS
ILEVRO (nepafenac) DROPS	bromfenac sodium drops
ketorolac tromethaminedrops	BROMSITE (bromfenac sodium) DROPS
NEVANAC (nepafenac) DROPS	
PROLENSA (bromfenac) DROPS – *Brand Required*	

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 an 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)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
XIIDRA (lifitegrast)		cyclosporine dropperette
		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 6-month trial of Restasis (cyclosporine) and a 2-month trial of Xiidra (lifitegrast)t, 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 (cyclosporine) and a 2-month trial of Xiidra (lifitegrast), and a 1-month trial of Tyrvaya (varenicline) 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
LUMIFY (brimonidine) 0.03% DROPS	IOPIDINE (apraclonidine) 1% DROPS

SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETOPTIC S (betaxolol) 0.25% DROPS	betaxolol 0.5% drops
carteolol drops	BETIMOL (timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS *– Brand Name Required*	brimonidine/timolol drops
dorzolamide/timolol drops	COSOPT (dorzolamide/timolol) PF DROPS
ISTALOL (timolol maleate) DROPS ONCE DAILY *– Brand Required*	timolol drops once daily
levobunolol drops	timolol gel forming solution
timolol maleate drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate/PF drops 0.5%	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) 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	TRUSOPT (dorzolamide)
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.
- Documentation of medical necessity must be provided, 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

- Documentation must be provided including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

CLINICAL PA REQUIRED
LUXTURNA (alglucosidase alfa) – *Medical Billing Only*

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 (as evidenced with submitted documentation)
- 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

Adalimumab

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

adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

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:
  - 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- VEGF Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BEOVU (brolucizumab-dbll) – *Medical Billing Only*	BYOOVIZ (ranibizumab -nuna) – *Medical Billing Only*
CIMERLI (ranibizumab-eqrn) – *Medical Billing Only*	LUCENTIS (ranibizumab) – *Medical Billing Only*
EYLEA (aflibercept) – *Medical Billing Only*	SUSVIMO (ranibizumab) – *Medical Billing Only*
VABYSMO (faricimab-svoa) – *Medical Billing Only*	

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

Non-Preferred Agent Criteria:

- Byooviz, Lucentis and Susvimo Only: See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (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
ZTLIDO (lidocaine) 1.8% PATCH	

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	COXANTO (oxaprozin)
diclofenac sodium DR 50 mg, 75 mg	CELEBREX (celecoxib)
etodolac	DAYPRO (oxaprozin)
flurbiprofen	diclofenac potassium 25 mg tablet
ibuprofen	diclofenac potassium 25 mg capsule
indomethacin	diclofenac sodium 25 mg DR
indomethacin ER	diclofenac sodium 100 mg ER tablet
ketoprofen IR	diclofenac/misoprostol
ketorolac	DUEXIS (famotidine/ibuprofen)
meclofenamate	etodolac ER
mefenamic acid	famotidine/ibuprofen
meloxicam	FELDENE (piroxicam)
nabumetone	fenoprofen
naproxen	INDOCIN (indomethacin)
piroxicam	ketoprofen ER 200 mg
sulindac	LOFENA (diclofenac potassium)
tolmetin	meloxicam, submicronized
VIMOVO (naproxen/esomeprazole) – *Brand Required*	MOBIC (meloxicam)
	NALFON (fenoprofen)
	NAPRELAN (naproxen)
	naproxen ER 500 mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)

	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

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
FLECTOR (diclofenac) 1.3% PATCH – *Brand Required*	diclofenac topical solution (labeler 59088)
	LICART (diclofenac) PATCH 1.3%

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Opioid Analgesics

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).
- Nucynta and Nucynta ER are not allowed with other narcotic medications
- 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 - *Brand Required*	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	CONZIP (tramadol ER) CAPSULES
OXYCONTIN (oxycodone) – *Brand Required*	hydrocodone ER tablets
tramadol ER Tablets	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER capsules
	XTAMPZA ER (oxycodone)

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, 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
NUCYNTA (tapentadol) TABLET	oxycodone 10mg tablet (Roxybond generic)
oxycodone 5 mg, 10 mg tablet	oxycodone 15 mg, 20 mg, 30 mg tablet
oxymorphone tablet	ROXICODONE (oxycodone) TABLET

tramadol 50 mg tablet	ROXYBOND (oxycodone) TABLET
	tramadol 25mg tablet
	tramadol 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 Only*

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:
  A. 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.
  B. 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 30-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	DEXEDRINE SPANSULE ER (dextroamphetamine)
lisdexamfetamine – *Generic Preferred*	
VYVANSE (lisdexamfetamine) – *Generic Preferred, Brand Allowed*	
High-Cost Options	
dextroamphetamine/amphetamine ER (generic Mydayis ER)	DYANAVEL XR (amphetamine)
	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 (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADZENYS XR – ODT (amphetamine)	amphetamine ER suspension
DYANAVEL XR (amphetamine) SUSPENSION	
lisdexamfetamine chew – *Generic Preferred*	
High-Cost Options	
VYVANSE (lisdexamfetamine) CHEW TABLET – *Generic Preferred, Brand Allowed*	
XELSTRYM (dextroamphetamine) PATCH	

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROCENTRA (dextroamphetamine) SOLUTION – *Brand Required*	dextroamphetamine 5 mg/5 ml

Methylphenidate

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOCALIN XR (dexmethylphenidate) - *Brand Name Allowed, Generic Preferred*	CONCERTA (methylphenidate)
dexmethylphenidate ER - *Brand Name Allowed, Generic Preferred*	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
methylphenidate CD 30-70	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg
methylphenidate ER tablet (generic Concerta)	
methylphenidate ER tablet (generic Metadate CD)	
RITALIN LA (methylphenidate LA capsules – 50-50) - *Brand Name Required*	
High-Cost Options	
AZSTARYS (serdexmethylphenidate/dexmethylphenidate)	APTENSIO XR (methylphenidate)
JORNAY PM (methylphenidate)	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)
methylphenidate ER capsule (generic Aptensio XR)	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 *– Brand Required*	methylphenidate patch
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
High-Cost Options	
	COTEMPLA XR – ODT (methylphenidate)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) SOLUTION
methylphenidate solution	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of each preferred medication under the same release and form group.

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 products are not allowed with short-acting products:
- 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

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 antidepressant medications (exceptions: trazodone and mirtazapine)
- 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 *– Brand Co-Preferred*	
High-Cost Options	
aripiprazole ODT	ABILIFY DISCMELT (aripiprazole)
aripiprazole solution	
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)	RYKINDO ER (risperidone microspheres)
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	
PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone microspheres) *– Brand Required*	
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
  - 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

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:
  A. PA Not Required Criteria: A 7-day supply of eszopiclone has been paid within 90 days prior to Belsomra's date of service.
  B. PA Required Criteria: The member must have failed 7-day trial of eszopiclone, as evidenced by paid claims or pharmacy printouts.
- Zolpidem:

A. PA Not Required Criteria: A 7-day supply of zolpidem 5mg has been paid within 90 days prior to zolpidem 10mg's date of service.
B. PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg, 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.
- Documentation is submitted of genetic testing confirming 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.

Pulmonary

Asthma/COPD

Therapeutic Duplication

- 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.

Albuterol / Levalbuterol Rescue Inhalers

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

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.

Electronic Step Therapy Required

- Levalbuterol HFA:
  A. 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.
  B. 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.
  A. 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).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.
  A. 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.

References:

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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)		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 Only*
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

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 Only*	

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 Only*	

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 previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) 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 and Cinqair Only*:
  - The member must have failed a 3-month trial of a preferred Anti-IL-5 biologic, as evidenced by paid claims or pharmacy printouts
  - The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

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

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.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

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)	BREO ELLIPTA (fluticasone/vilanterol)	BREYNA (budesonide/formoterol)

– Brand Required	*– Brand Required*	
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/Short-Acting Beta Agonist (SABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	AIRSUPRA (albuterol/budesonide)

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.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of Symbicort and Dulera, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred Steroid/LABA or SABA agents (subject to clinical review).

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) + Incluse 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.
- 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.
- The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting anticholinergic and has a contraindication or intolerance to a long-acting beta agonist (subject to clinical review)
- The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting beta agonist and has a contraindication or intolerance to a long-acting anticholinergic (subject to clinical review)

Cystic Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETHKIS (tobramycin) – *Brand Required*	ARIKAYCE (amikacin/nebulizer)
tobramycin (generic Tobi)	CAYSTON (aztreonam)
	KITABIS PAK (tobramycin/nebulizer)
	TOBI (tobramycin)
	TOBI PODHALER (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.

Cystic Fibrosis – CFTR Modulators

CLINICAL PA REQUIRED
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, as evidenced by medical documentation (e.g., chart notes, genetic testing) that is attached to the request.

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 prescriber must submit documentation of the following:
  - 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
cyclophosphamide	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
mycophenolate mofetil (MMF)	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
	TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE
	TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	OFEV (nintedanib)
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - 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.

Rheumatology

Axial Spondyloarthritis/Ankylosing Spondylitis

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

	SIMPONI ARIA (golimumab)– *Medical Billing Only*

Interleukin (IL) – 17 Inhibitors

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

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 a TNF Inhibitor 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

- Cimzia Only: The member must have failed a 90-day trial of a TNF inhibitor, 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, 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,Taltz, as evidenced by paid claims or pharmacy printouts.
- Inflectra, infliximab, Remicade, 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

Adalimumab

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

adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

Prior Authorization Criteria

1. See Preferred Dosage Form 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 Only*

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 (as evidenced by documentation):
  - 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 Only*

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 (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
	TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE
	TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

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 Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)

	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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.
- Biosimilars Only: See Preferred Dosage Form criteria

Juvenile Idiopathic Arthritis – Polyarticular Course

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
	TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE
	TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	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) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – *Medical Billing Only*

TNF Inhibitors

Adalimumab

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

adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab) – *Medical Billing Only*

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, Orencia, as evidenced by paid claims or pharmacy print outs.
- Rinvoq ER Only: The member has failed a 3-month trial of a TNF inhibitor, Orencia, and Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Biosimilars and Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Simponi Aria Only: The member must have failed a 30-day trial of Rinvoq ER, and Xeljanz and a 90-day trial of a TNF inhibitor and Orencia, 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)

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – *Medical Billing Only*

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
	TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE

	TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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.
- *Ilaris Only:* The member has failed a 3-month trial of tocilizumab, as evidenced by paid claims or pharmacy print outs.

References:

1. Dewitt, E.M., Kimura, Y., Beukelman, T., Nigrovic, P.A., Onel, K., Prahalad, S., Schneider, R., Stoll, M.L., Angeles-Han, S., Milojevic, D., Schikler, K.N., Vehe, R.K., Weiss, J.E., Weiss, P., Ilowite, N.T., Wallace, C.A. and (2012), Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res, 64: 1001-1010. https://doi.org/10.1002/acr.21625

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

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab)– *Medical Billing Only*

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 Only*
	ORENCIA (abatacept) – 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 Only*

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)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor 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:
Cosentyx Only:
- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

All Other Agents:
- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor (etanercept)
  - Interleukin (IL) – 17 inhibitor (secukinumab)

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
- Skyrizi: 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
- Interleukin (IL)-12/IL-23 Inhibitor, Bimzelx, Simponi Aria, 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
    - 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)
RIABNI (rituximab-arrx) – *Medical Billing Only*	
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*
	TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE
	TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KEVZARA (sarilumab)

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 Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab)– *Medical Billing Only*

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
  - T-cell Co-stimulation Blocker
- Simponi Aria: The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - T-cell Co-stimulation Blocker
  - Rinvoq ER
  - Interleukin – 6 inhibitors
- Xeljanz IR 10mg, Xeljanz XR: 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 Only*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

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:
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form Criteria

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.
- Documentation must be attached to confirm one of the following:
  - Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
  - 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

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 Only*	FOSAMAX (alendronate)
ibandronate – *Medical Billing Only*	FOSAMAX D (alendronate/vitamin D)
RECLAST (zolendronic acid) – *Medical Billing Only*	risedronate DR
risedronate IR	
zoledronic acid – *Medical Billing Only*	

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 Only*	

++ 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 Only*	

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 Only*	

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 (as evidenced by submitted documentation) 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 documentation of 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

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	
nalmefene injection	
naloxone injection	
naloxone nasal spray	
OPVEE (nalmefene) NASAL SPRAY	
REXTOVY (naloxone) NASAL SPRAY	
ZIMHI (naloxone) SYRINGE	

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	Injection #1	Injection #2	Maintenance Dose
8 – 18 mg/day	300 mg	100 mg*	100 mg
20 – 24 mg/day	300 mg	300 mg	100 mg
*For patients still experiencing craving or withdrawal symptoms after the initial 300-mg dose, consider giving 300 mg as the second dose			

Sublocade is not indicated when established transmucosal buprenorphine dose is under 8 mg/day. Brixadi has dosing recommendations when established transmucosal buprenorphine dose is under 8 mg/day.

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
  A. methadone
  B. carisoprodol
  C. 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 DAW (Dispense As Written) Criteria

Preferred Dosage Forms 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.
- 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

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
	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

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
EOHILIA (budesonide)	deflazacort
hydrocortisone	EMFLAZA (deflazacort) – *Brand Required*

methylprednisone	HEMADY (dexamethasone)
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	MILLIPRED (prednisolone)
prednisone solution	ORTIKOS (budesonide)
prednisone tablets	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
LifeScan Inc.	53885-0244-50	OneTouch Ultra Blue
LifeScan Inc.	53885-0245-10	OneTouch Ultra Blue
LifeScan Inc.	53885-0270-25	One Touch Verio Test Strip
LifeScan Inc.	53885-0271-50	One Touch Verio Test Strip
LifeScan Inc.	53885-0272-10	One Touch Verio Test Strip
LifeScan Inc.	53885-0994-25	OneTouch Ultra Blue
Ascensia Diabetes Care	00193-7080-50	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7090-21	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7311-50	Contour Next Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7312-21	Contour Next Blood Glucose Test Strips

Meters

Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
LifeScan Inc.	53885-0044-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0046-01	OneTouch Ultra 2 Blood Glucose Meter
Ascensia Diabetes Care	00193-7553-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7825-01	Contour Next One Blood Glucose Monitor
Ascensia Diabetes Care	00193-7917-01	Contour Next Gen Blood Glucose Monitor
Ascensia Diabetes Care	00193-7922-01	Contour Next Gen Blood Glucose Monitor
Ascensia Diabetes Care	00193-9545-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9628-01	Contour Next EZ Blood Glucose Meter

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)

Syringes

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3284-11	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-18	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-31	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-38	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-40	BD syrge-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3284-66	BD syringe-needle,insulin,0.5 mL

Becton Dickinson & Company	08290-3284-68	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3267-30	BD syringe,insul U-500,ndl,0.5mL
Becton Dickinson & Company	08290-3249-06	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-07	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-08	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3249-09	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-10	BD syringe-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3249-11	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-12	BD syringe and needle,insulin,1mL
Ultimed Inc.	08222-0941-93	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0741-95	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0931-58	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	57515-0093-15	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0921-99	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	57515-0092-19	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0945-99	Ulticare syringe-needle,insulin,0.5 mL
Ultimed Inc.	08222-0745-91	Ulticare syringe-needle,insulin,0.5 mL
Ultimed Inc.	08222-0943-91	Ulticare syring-needl,disp,insul,0.3 mL
Ultimed Inc.	57515-0094-39	Ulticare syring-needl,disp,insul,0.3 mL

Ketone Strips

Quantity Limits

- 120 strips per 30 days

Manufacturer Name	NDC	Product Description
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 have 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 15 sensors (3 boxes) per 90-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 15 sensors (3 boxes) per 90-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 as provided in submitted documentation.

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 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 already have a Medtronic insulin pump 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 08508300053 - Omnipod 5 G6-G7 Pods (Gen 5) - 10 pods per 30-day supply
- NDC 08508300050 - Omnipod 5 G6-G7 Intro Kit - 1 per 30-day supply (payable 1 per 365 days)
- 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.	08508-3000-53	Omnipod 5 G7 Pack Pods
Insulet, Inc.	08508-3000-50	Omnipod 5 G7 Intro Kit
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
  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.
- 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. The group will need to be changed from the SHS group to the ND Medicaid group.
- ND Medicaid has pre-emptively entered initial prior authorizations for SHS members utilizing Omnipod for 1 year. ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the grandfathering period.

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. Documentation of 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
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	Eosinophilic asthma 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
09/02/2015	cholesterol lowering drugs/PCSK9 inhibitors
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
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
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