Preferred Drug List (PDL)

Preferred Diabetic Supply List (PDSL)

Medical Billing Drug Clinical Criteria

Including:

Prior Authorization Criteria

Therapeutic Duplication

Electronic Step Care and Concurrent Medications

First Fill

Underutilization

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Table of Contents:

Drug Utilization Review policies:

- Length of prior authorizations is a year unless otherwise specified.
- 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.
- Prior authorization for a non-preferred agent in any category will be given only if all other criteria is met, including clinical criteria and step therapy specific to that category.
- 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).
- A trial will be considered a failure if a product was not effective at maximum tolerated dose with good compliance, as evidenced by paid claims or pharmacy print outs or member has a documented contraindication, intolerance, or adverse reaction to an ingredient
- Unless otherwise specified, the listing of a brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.
- Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
- 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).
- Initial prior authorization criteria must be met for renewal requests, as applicable.

*** Indicates that additional PA criteria applies as indicated in the Product PA Criteria

Contents

Major Changes Since Last Version

Albuterol/Levalbuterol Rescue Inhalers
- electronic step added to Xopenex

Aplastic Anemia
- Renewal criteria added

Chronic hepatitis C infection-associated thrombocytopenia
- Initial criterion added
- Renewal criteria added

Cystic Fibrosis:
- Bronchitol added to prior authorization with Bronchitol Tolerance Test requirement

Diabetes
- Sulfonylureas and TZDs are covered together

Empaveli
- Hb level added for renewal criteria

Eosinophilic asthma
- Eosinophil and IgE levels added to criteria

Glucose Rescue Medications
- Added step therapy

Huntington's Disease
- Added step therapy

Narcolepsy
- Criteria added specific to Xywav

Insulins
- Regular insulin criteria added
- Humalog U-200 criteria added
- TZDs are allowed with insulin

Otezla
- Preferred for all indications

Parkinson's Disease
- Renewal therapy added

Plaque Psoriasis:
- Anti-interleukin (IL) 17 Antibodies - Taltz and Cosentyx: Require 3-month trial of a TNF Inhibitor
- Otezla covered for all indications without prior authorization

Steroid/Anticholinergic/Long-Acting Beta Agonist Combination:
- Step Therapy added with the entry of competitor

Taltz:
- Require electronic step therapy

Xeljanz
- Preferred for all indications

Preferred Drug List (PDL)

General

Biosimilar Agents

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Combination Agents

General Prior Authorization Form

Group Criteria:

- Clinical justification must be provided for combination products that are comprised of components available and more cost effective when prescribed separately (subject to clinical review).

Dispense as Written (DAW1)

Prior Authorization Form - Dispense As Written (DAW1)
MedWatch Form

Criteria for ALL DAW requests (must meet one of the following (A or B):

A. Primary insurance requires a ND Medicaid non-preferred branded product
   - *Approval Duration: 12 months*

B. All of the following are met (1-4):
   1. The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
   2. The requested brand-name product must not have an authorized generic available
   3. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product from each available manufacturer, as evidenced by paid claims or pharmacy print outs
      a. A failure is defined as product was not effective at maximum tolerated dose or caused adverse reaction where the branded product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the member
      b. The member or prescriber preference is NOT criteria considered for approval
   4. A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request

Medications that cost over $3000/month

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a specialist, or the prescriber has consulted with a specialist in the area of the member's diagnosis
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment

- **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).

PA REQUIRED
BYLVAY (odevixibat)
CERDELGA (eliglustat)
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DOJOVI (triheptanoin)
ENSPRYNG (satralizumab)
FIRDAPSE (amifampridine)
GATTEX (teduglutide)
INCRELEX (mecasermin)
KOSELUGO (selumetinib)
LUPKYNIS (voclosporin)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
RAVICTI (glycerol phenylbutyrate)
REZUROCK (belumosudil)
SAMSCA (tolvaptan)
SYPRINE (trientine)
TAVNEOS (avacopan)
WELIREG (belzutifan)
ZOKINVY (lonafamib)

Non-solid dosage preparations

General Prior Authorization Form

Electronic Age Verification

A. Non-solid dosage preparations of preferred products are automatically covered for all members younger than 9 years old. For coverage of these products in members 9 years of age or older, one of the following criteria must be met (A or B): The member is unable to swallow solid dosage medications due to one of the following:
   - Swallow study documentation – *Approval 1 year*
   - Feeding tube placement and the medication is not available in a dosage form that can be crushed or poured into the tube – *Approval 1 year*
   - Permanent disability of swallowing solid dosage forms - A*pproval 2 years*
   - Short-term restriction (e.g. mouth surgery) - *Approval 1 month*

B. Clinical justification has been provided as to why a solid dosage medication cannot be used (subject to clinical review)

Preferred Dosage Forms List:

General Prior Authorization Form

See Preferred Dosage Forms List

Allergy/Immunology

Biologic Agents

Chronic Idiopathic Urticaria

General Prior Authorization Form

Category Criteria (Initial): *Approval Duration = 3 months*

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have had a 30-day trial of a type 1 (H1) antihistamine at maximally tolerated dose either non-sedating (e.g. cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine) or sedating (e.g. diphenhydramine, chlorpheniramine, cyproheptadine) in addition to one of the following:
    - leukotriene receptor antagonist (e.g. montelukast, zafirlukast, zileuton)
    - histamine H2-receptor (e.g. ranitidine, famotidine, nizatidine, cimetidine)

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a clinical benefit since treatment initiation.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGES	

Medical Billing Drug Clinical Criteria Only

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) VIALS	

Eosinophilic Asthma

General Prior Authorization Form

Category Criteria (Initial): *Approval Duration = 3 months*

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist
- The member must have had at least one exacerbation despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Product Specific Criteria (Initial):

- Anti-IL-5 and Anti-IL-4/13 biologics:
    - The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- Eosinophil-directed biologics:
    - The member has a serum total IgE level, measured before the start of treatment, 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

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of 1 preferred Eosinophilic Asthma agent, as evidenced by paid claims or pharmacy printouts

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab) PEN	NUCALA (mepolizumab)

Anti-IL-4/13 biologics

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

Eosinophil-directed biologics:

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGES	

Eosinophilic granulomatosis with polyangiitis (EGPA)

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The member must be 18 years of age or older
  - The prescription must be written by, or in consultation with, a hematologist, pulmonolgist, or allergy/immunology specialist
  - The member must have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) characterized by
    - Member has asthma poorly controlled on moderate doses of inhaled glucocorticoids
    - Member has a greater than blood eosinophilia > 1000 cells/mcL or 10% eosinophils on the differential leukocyte count, as evidenced by laboratory documentation attached to the request
    - Two of more of the following:
      - Mononeuropathy (including multiplex) or polyneuropathy
      - Pulmonary infiltrates
      - Paranasal sinus abnormality
      - Eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
      - Glomerulonephritis
      - Alveolar hemorrhage
      - Palpable purpura
      - Myocardial infarction due to coronaritis
      - Anti-neutrophil cytoplasmic antibody (ANCA) positivity
  - The member must have had relapsing or recurring disease requiring systemic corticosteroids in previous year despite a 3-month trial with good compliance of one of the following medication, as evidenced by paid claims or pharmacy printouts:
    - Cyclophosphamide
    - Azathioprine
    - Methotrexate
    - Leflunomide
- **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)

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

NUCALA (mepolizumab)	

Hypereosinophilic Syndrome

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The member must be 12 years of age or older
  - The prescription must be written by, or in consultation with, a hematologist, or allergy/immunology specialist
  - The member must have a diagnosis of hypereosinophilic syndrome (HES) characterized by the following:
    - The member must have experienced hypereosinophilic syndrome for ≥6 months
    - The provider must attest that there is no identifiable nonhematologic secondary cause
  - The member must have experienced at least 2 HES flares within the past 12 months despite continued compliant use of oral corticosteroids and/or steroid sparing therapy (e.g. hydroxyurea)
  - The member must have a blood eosinophil count of 1,000 cells/mcL or higher, as evidenced by laboratory documentation attached to the request
- **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)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCALA (mepolizumab)	

Nasal polyps

General Prior Authorization Form

Category Criteria (Initial): *Approval Duration = 3 months*

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have had a 12-week trial of intranasal or oral corticosteroid
- The member must have bilateral polyps confirmed by sinus CT, sinus MRI, or nasal endoscopy
- Member must have documentation of at least two of the following symptoms:
  - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
  - Facial pain/pressure
  - Reduction or loss of smell

Non-Preferred Agent Criteria:

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

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NUCALA (mepolizumab)
XOLAIR (omalizumab) SYRINGES	

Epinephrine

Electronic Duration Verification

- 3 packs (initial and replacement doses) are covered every 180 days without prior authorization.

General Prior Authorization Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epinephrine – labeler 49502	epinephrine – labeler 00935
SYMJEPI (epinephrine)	epinephrine – labeler 11516
	EPIPEN (epinephrine)
	EPIPEN (epinephrine) JUNIOR

Gout

Krystexxa (pegloticase) – Medical Billing Drug Clinical Criteria

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

- **Colchicine capsules:**
  - See **Preferred Dosage Form List** Criteria
- **Febuxostat:**
  - The member must have had a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
allopurinol tablet	colchicine capsules
COLCRYS (colchicine) TABLETS – *Brand Required*	colchicine tablets
probenecid-colchicine tablets	febuxostat
probenecid tablets	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE
	ULORIC (febuxostat) TABLET
	ZYLOPRIM (allopurinol) TABLET

Hereditary Angioedema

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The medication must be prescribed by or in consultation with an allergist, immunologist, or rheumatologist

Non-Preferred Agents Criteria:

- The request must meet the group criteria
- The member must have a contraindication to or failed a trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts
  - Required trial durations
    - Agents for acute attacks: a single trial
    - Agents for attack prophylaxis: 3 months

Product Specific Criteria:

- Takhyzro
  - The number of attacks in the last 6 months must be included if the requested dose is 300mg every 2 weeks.

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BERINERT (C1 Esterase Inhibitor)	FIRAZYR (icatibant)
Icatibant	KALBITOR (ecallantide)
RUCONEST (C1 Esterase Inhibitor)	

Prophylaxis

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

Immune Globulins

General Prior Authorization Form

Category Criteria:

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose
- The member must have a diagnosis of an FDA-approved indication for use

Non-Preferred Product Specific Criteria:

- 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)

IVIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin gamma)	ASCENIV (human immune globulin G- slra)
FLEBOGAMMA DIF (human immunoglobulin gamma)	GAMMAPLEX (human immunoglobulin gamma)
GAMMAGARD S-D (human immunoglobulin gamma)	OCTAGAM (human immunoglobulin gamma)
PRIVIGEN (human immunoglobulin gamma)	PANZYGA (Immune Globulin- ifas)

IVIG/SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	GAMMAKED (human immunoglobulin gamma)
GAMUNEX-C (human immunoglobulin gamma)	

SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HIZENTRA (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G - hipp)
	CUVITRU (human immunoglobulin gamma)
	HYQVIA (human immune globulin G and hyaluronidase)

Palforzia

Palforzia Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The member does not have any contraindications to treatment
  - The prescriber must be or be in consultation with an allergy and/or immunology specialist
  - 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 must not have any of the following:
    - Uncontrolled asthma
    - A history of eosinophilic esophagitis or another eosinophilic GI disease

        - Severe or life-threatening anaphylaxis in the 60 days prior to the request
    - The member must have a clinical history of allergy to peanuts or peanut-containing foods AND one of the following:
        - The member has had a serum immunoglobulin E (IgE) to peanut ≥0.35 kUA/L
        - Skin prick test (SPT) to peanut ≥ 3mm compared to control
        - Allergic reaction produced during a provider observed intake of peanuts
- **Renewal Criteria:** *Approval Duration = 6 months for continued up-titration or 12 months for maintenance the 300mg dose*
    - The member must have been compliant with Palforzia, as evidenced by pharmacy records or pharmacy claims history showing on-time fills during the last 6 months
    - The member must not have any of the following:
        - Uncontrolled asthma
        - Severe or persistent GI symptoms
        - Eosinophilic esophagitis
    - The member must have experienced and maintained clinical benefit since starting treatment with Palforzia, as evidenced by the following:
        - The member continues to have a peanut allergy and has been/is being monitored for resolution of their allergy
        - The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily)
          OR
        - The prescriber has submitted a plan to continue up-titration to a final dose of 300 mg daily and have not already requested a renewal PA for the up-titration period

PA REQUIRED
PALFORZIA (peanut allergen powder)

Steroids - Nasal

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial (within the past 2 years) of 1 preferred agent, as evidenced by paid claims or pharmacy printouts

Product Specific Criteria:

- ***Xhance (fluticasone):**
    - Clinical justification must be provided explaining why the member is unable to use another product with the same active ingredient (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BECONASE AQ (beclomethasone)	flunisolide
Fluticasone	mometasone
OMNARIS (ciclesonide)	XHANCE (fluticasone)***
QNASL (beclomethasone)	
QNASL CHILDREN'S (beclomethasone)	
ZETONNA (ciclesonide)	

Cardiology

Therapeutic Duplication

- One Strength of one medication is allowed at a time
    - Exceptions:

        - Carvedilol IR 25mg 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 alpha blockers (Alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, and tamsulosin)
        - Carvedilol and Labetalol are nonselective 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).

Beta Blockers – Override Request

Please have the following information when requesting an override by calling provider relations at 1-800-755-2604. Overrides may be available for beta blockers with slightly different mechanisms of action for use within the cardiac or nephrology specialty: non-selective or selective beta blocking activity; with or without alpha-1 blocker activity.

1. Are prescribers of each medication aware of the other?
2. Is a cardiologist and/or nephrologist involved in therapy who agrees to duplication?

Anticoagulants - Oral:

Underutilization

- Eliquis, Pradaxa, Xarelto, and Savaysa must be used compliantly and will reject on point of sale for late fill

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

***Xarelto 2.5mg** - Member must have an FDA approved indication.

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication.
- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (Apixaban)	SAVAYSA (edoxaban)
PRADAXA (dabigatran)	
XARELTO (rivaroxaban) 10mg, 15mg, 20mg	
XARELTO (rivaroxaban) 2.5mg PA***	
XARELTO (rivaroxaban) STARTER PACK	

Anticoagulants - Injectable

Electronic Diagnosis Verification

- Fondaparinux is covered for a diagnosis of heparin-induced thrombocytopenia (HIT)

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
fondaparinux	FRAGMIN (dalteparin)
	LOVENOX (enoxaparin)

Heart Failure

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo require an FDA-approved indication for use.

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

- **Verquvo:**
  - The member must meet FDA-approved age for use.
  - The member must have left ventricular ejection fraction (LVEF) < 45%
  - Documentation of a recent hospitalization or need for IV diuretics (within the past 6 months) must be submitted with request
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- **Corlanor:**
  - The member must meet FDA-approved age for use.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm

AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred*	
ARBs (angiotensin receptor blockers) - *all oral agents preferred*	
Beta blockers - *all oral agents preferred*	
CORLANOR (ivabradine) PA	
ENTRESTO (sacubitril/valsartan)	
eplerenone	
FARXIGA (dapagliflozin)	
JARDIANCE (empagliflozin)	
spironolactone	
VERQUVO (vericiguat) PA	

Loop Diuretics

General Prior Authorization Form

Product Specific Criteria:

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

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

Lipid-Lowering Agents

General Prior Authorization Form

Non-Preferred Agent Criteria (Initial): *Approval Duration = 3 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have LDL levels of >100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - A PCSK9 inhibitor combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg

Product Specific Criteria:

- Evkeeza: See Medical Billing Drug Clinical Criteria
- **Juxtapid:**
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
    - The member must have LDL levels of >100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
        - A PCSK9 inhibitor combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
        - Nexlizet combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
    - Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

Group Criteria (Renewal): *Approval Duration = 12 months*

- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
- 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)

ACL (ATP Citrate Lyase) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NEXLETOL (bempedioc acid)
	NEXLIZET (bempedoic acid and ezetimibe)
Cholesterol Absorption Inhibitor - 2-Azetidinone	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Ezetimibe	ZETIA (ezetimibe)
MTP (Microsomal Triglyceride Transfer Protein) INHIBITOR	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	JUXTAPID (lomitapide)
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 capsules	ANTARA (fenofibrate, micronized)

fenofibrate tablets 48mg, 54mg, 145mg, 160mg	fenofibrate, micronized 30mg, 90mg
	fenofibrate tablets 40mg, 120mg
	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate)
	TRIGLIDE (fenofibrate)
PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PRALUENT PEN (alirocumab)	REPATHA PUSHTRONEX (evolocumab)
	REPATHA SURECLICK (evolocumab)
	REPATHA SYRINGE (evolocumab)
STATINS (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors)	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
amlodipine/atorvastatin	ALTROPREV (lovastatin)
atorvastatin	CADUET (amlodipine/atorvastatin)
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	EZALLOR SPRINKLE (rosuvastatin)
LIVALO (pitavastatin)	Fluvastatin ER
lovastatin	LESCOL XL (fluvastatin)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	PRAVACHOL (pravastatin)
simvastatin	VYTORIN (ezetimibe/simvastatin)
ZYPITAMAG (pitavastatin)	ZOCOR (simvastatin)

Platelet Aggregation Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 30-day trials of at least 2 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

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

Pulmonary Hypertension

PDE-5 Inhibitors

Electronic Age Verification

- Sildenafil/Tadalafil: Prior authorization is not required for ages less than 12 years old
- Revatio Suspension: Prior authorization is not required for ages less than 9 years old

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age), with medical documentation (e.g. clinical notes) of their diagnosis attached to the request.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REVATIO (sildenafil) SUSPENSION – *Brand Required*	ADCIRCA (tadalafil) TABLET
sildenafil tablet	ALYQ (tadalafil)
tadalafil tablet	REVATIO (sildenafil) TABLET
	sildenafil suspension

Soluble Guanylate Cyclase Stimulators

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

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

Endothelin Receptor Antagonists

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

Prior Authorization Criteria

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of ambrisentan, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	bosentan
TRACLEER (bosentan) SUSPENSION	LETAIRIS (ambrisentan)
TRACLEER (bosentan) TABLETS - *Brand Required*	OPSUMIT (macitentan)

Prostacyclins

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENITRAM ER (treprostinil) TABLET	REMODULIN (treprostinil) INJECTION
UPTRAVI (selexipag) TABLET	
treprostinil injection	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) VIAL	
VENTAVIS (iloprost) INHALATION	

Vecamyl

General Prior Authorization Form

Group Criteria:

- The member must have documented history of failure to achieve blood pressure goals (using maximum tolerated doses) of all first- and second-line agents as defined by the most recent JNC report.

Dermatology

Acne

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

Electronic Age Verification

- The member must be between 12 and 35 years of age

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

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	NEUAC (Clindamycin/benzoyl peroxide) 1.2%-5%
ONEXTON (Clindamycin/benzoyl peroxide) 1.2%-3.75%	
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) MED SWAB
clindamycin solution	CLINDACIN P (Clindamycin) MED SWAB
clindamycin med. swab	CLINDACIN ETZ (Clindamycin) MED SWAB
EVOCLIN (Clindamycin) FOAM – *Brand Required*	CLINDAGEL (Clindamycin) GEL DAILY
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	clindamycin gel daily
	clindamycin foam
	clindamycin-tretinoin 1.2%-0.025%
RETINOID	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ALTRENO (tretinoin) LOTION	ATRALIN (tretinoin) 0.05% GEL
FABIOR (tazarotene) 0.1% FOAM - *Brand Required*	ARAZLO (tazarotene) 0.045% LOTION
RETIN-A MICRO PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required*	clindamycin-tretinoin 1.2%-0.025%
RETIN-A MICRO PUMP (tretinoin microsphere) 0.08%	RETIN-A (tretinoin) CREAM
tretinoin cream	RETIN-A (tretinoin) GEL
tretinoin gel	RETIN-A MICRO PUMP (tretinoin microsphere) 0.06%
tretinoin microsphere without pump	RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP
ZIANA (clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	tazarotene 0.1% foam
	tretinoin microsphere with pump

ADAPALENE	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
adapalene gel	adapalene cream
adapalene gel with pump	adapalene/benzoyl peroxide 0.3%-2.5%
adapalene/Benzoyl Peroxide 0.1%-2.5%	DIFFERIN (adapalene) GEL
DIFFERIN (adapalene) CREAM - *Brand Required*	DIFFERIN (adapalene) GEL W/ PUMP
DIFFERIN (adapalene) LOTION	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% - *Brand Preferred*	
OTHER	
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%
Cleansing Wash (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	AKLIEF (trifarotene) CREAM 0.005%
dapsone gel without pump 5%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
SSS 10-5 (sulfacetamide) FOAM	dapsone gel pump 7.5%
sulfacetamide 10% suspension	SSS 10-5 (sulfacetamide) CLEANSER
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	sodium sulfacetamide/sulfur pads 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	sodium sulfacetamide/sulfur cream 10%-2%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMADAN (sodium sulfacetamide/sulfur) CLEANSER 9%-4.5%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 10%-2%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
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%	
TETRACYCLINES	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
doxycycline hyclate capsule	AMZEEQ (minocycline) Foam
doxycycline hyclate tablet 20mg, 100mg	demeclocycline
doxycycline monohydrate 25 mg/5mL suspension	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75mg, 100mg	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate capsule 50 mg, 100mg	doxycycline monohydrate capsule 75mg, 150mg
minocycline capsule	doxycycline hyclate tablet 75mg, 150 mg
tetracycline	doxycycline monohydrate tablet 150 mg
VIBRAMYCIN (Doxycycline calcium) 50 mg/5mL SYRUP	doxycycline hyclate tablet DR
	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline Tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE
	SEYSARA (sarecycline)
	SOLODYN ER (minocycline) TABLET
	VIBRAMYCIN (doxycycline monohydrate) 25mg/5mL SUSPENSION
	XIMINO (minocycline) CAPSULE ER

Actinic Keratosis

General Prior Authorization Form

Product Specific Criteria:

- Diclofenac 3% sodium gel requires electronic diagnosis verification of FDA indication

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARAC (fluorouracil) 0.5% CREAM – *Brand Required*	ALDARA (imiquimod) 0.5% CREAM
diclofenac 3% sodium gel	EFUDEX (fluorouracil) 5% CREAM
imiquimod 5% cream packet	fluorouracil 0.5% cream
fluorouracil 5% cream	imiquimod 3.75% cream pump
fluorouracil 2% solution	KLISYRI (tirbanibulin) OINTMENT
fluorouracil 5% solution	PICATO (ingenol mebutate)
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required*	TOLAK (fluorouracil) 4% CREAM
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

Antifungals – Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Onychomycosis:** *Approval Duration = 12 months*
  - The member must have a diagnosis of an FDA approved indication for use
    - 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):
    A. Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
    B. The active ingredient of the requested product is not available in a preferred formulation
- **Other diagnoses:** *Approval Duration = 12 months*
  - The member must have had 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):
    A. Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
    B. The active ingredient of the requested product is not available in a preferred formulation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox cream	CICLODAN (ciclopirox) CREAM
ciclopirox gel	CICLODAN (ciclopirox) SOLUTION

ciclopirox shampoo	EXTINA (ketoconazole) FOAM
ciclopirox solution	JUBLIA (efinaconazole) SOLUTION
ciclopirox suspension	KERYDIN (tavaborole) SOLUTION
clotrimazole cream	ketoconazole foam
clotrimazole solution	LOPROX (ciclopirox) CREAM
econazole cream	LOPROX (ciclopirox) SHAMPOO
ERTACZO (sertraconazole) CREAM	LOPROX (ciclopirox) SUSPENSION
EXELDERM CREAM (sulconazole) – *Brand Required*	LUZU (luliconazole) Cream
EXELDERM SOLUTION (sulconazole) – *Brand Required*	miconazole/zinc oxide/white petrolatum ointment
ketoconazole cream	natfifine Cream
ketoconazole shampoo	natfifine Gel
luliconazole cream	NAFTIN (naftifine) CREAM
MENTAX (butenafine) CREAM	NAFTIN (naftifine) GEL
miconazole cream	oxiconazole cream
nystatin cream	OXISTAT (oxiconazole) CREAM
nystatin ointment	OXISTAT (oxiconazole) LOTION
nystatin powder	tavaborole solution
NYAMYC (nystatin) POWDER	VUSION (miconazole/zinc/white petrolatum) OINTMENT
nystatin – triamcinolone cream	
nystatin – triamcinolone ointment	
NYSTOP (nystatin) POWDER	

Eczema / Atopic Dermatitis

Electronic Age Verification

Product Specific: Protopic (tacrolimus) ointment 0.1%

- The member must be 16 years of age or older

Prior Authorization Criteria

Topical Corticosteroids: Please see the Preferred Drug List of Topical Corticosteroids

Product Specific Criteria (Initial): *Approval Duration = 3 months*

- **Eucrisa, Dupixent, and Opzelura**
  - Member must meet FDA label recommendations for indication and age
  - Member must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy printouts:
    - tacrolimus OR pimecrolimus
  - One of the following must be met (A or B):
    A. Member must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    B. Member must meet both of the following (1 AND 2):
       1. Affected area is on face, groin, axilla, or under occlusion
       2. Member must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.
  - **Opzelura**: *Approval Duration = 3 months*
    - Indicated for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis.
    - The member must have a percentage BSA (excluding scalp) with AD involvement of 3% - 20%.

- The member must not be immunocompromised.
- The member must have had a 3-month trial of Eucrisa ointment, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria (Renewal): *Approval Duration = 12 months*

- **Eucrisa and Dupixent**
  - The prescriber must submit documentation showing that the member has achieved a significant reduction in severity of atopic dermatitis since treatment initiation

Biologics

Prior Authorization Form - Dupixent

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

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclosporine	
methotrexate	
systemic oral corticosteroids	

Topical

General Prior Authorization Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIDEL (pimecrolimus) CREAM – *Brand Required*	EUCRISA (crisaborole) OINTMENT***
PROTOPIC (tacrolimus) OINTMENT 0.03% – *Brand Required*	OPZELURA (ruxolitinib) 1.5% CREAM
PROTOPIC (tacrolimus) OINTMENT 0.1% – *Brand Required*	pimecrolimus
Topical Corticosteroids	tacrolimus 0.03%
	tacrolimus 0.1%

Hidradenitis Suppurativa

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

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

Infantile Hemangioma

Electronic Age Verification

- The patient must be less than 1 years of age

Electronic Diagnosis Verification

- The patient must have an FDA approved diagnosis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMANGEOL (propranolol) ORAL SOLUTION	

Lice

General Prior Authorization Form

Category Criteria:

- The member must have had a 28-day/2-application trial of each preferred agent, as evidenced by paid claims or pharmacy printouts (not required *in the presence of a documented community breakout of a resistant strain that is only susceptible to a non-preferred agent).*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EURAX (crotamiton) CREAM	CROTAN (crotamiton)
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	ELIMITE (permethrin) CREAM
NIX 1% (Permethrin) CRÈME RINSE LIQUID	EURAX (crotamiton) LOTION
Permethrin 5% cream	Lindane shampoo
SM LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	Malathion
Spinosad	NATROBA (spinosad)
VANALICE (piperonyl butoxide/pyrethrins)	OVIDE (malathion)

Plaque Psoriasis

Biologic Agents

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Concurrent Medication and Step Care

- Taltz***
  - A total of 90 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of a TNF inhibitor and an Anti-IL 17 agent, as evidenced by paid claims or pharmacy printouts.

Anti – TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	

Anti – Interleukin (IL) 12/IL-23

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

Anti – Interleukin (IL) 17 Antibodies

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)***	COSENTYX (secukinumab)

Anti – Interleukin (IL) 17 Receptor Antibody

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

Anti – Interleukin (IL) 23/ Interleukin (IL) 39

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

Phosphodiesterase 4 (PDE4) Inhibitor

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

Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **For Foams and Sprays:**
  - Member must have failed 30-day trials of the preferred solution and shampoo formulations, as evidenced by paid claims or pharmacy print outs
- **For Lotions:**
  - Member must have failed a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy print outs
- **For Ointments:**
  - Member must have failed 30-day trials of the preferred ointment formulations, as evidenced by paid claims or pharmacy print outs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcipotriene/betamethasone ointment
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene cream	calcipotriene foam
ENSTILAR (calcipotriene/betamethasone) FOAM	calcitriol ointment
SORILUX (calcipotriene) FOAM – *Brand Required*	DOVONEX (calcipotriene) CREAM
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	DUOBRII (halobetasol/tazarotene) LOTION
TACLONEX (calcipotriene/betamethasone) OINTMENT – *Brand Required*	
tazarotene 0.1% cream	
VECTICAL (calcitriol) OINTMENT – *Brand Required*	

Steroids - Topical

Electronic Duration Verification

Class 1 topical steroids are covered for 30 days every 90 days. Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Class 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. Class 1 steroids are covered with class 2 steroids to facilitate an alternating schedule.
- Please call for an override if the following conditions apply by calling provider relations at 1-800-755-2604:
  - Location of application: palms and soles
  - Indication: psoriasis
  - Close monitoring for side effects

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Non-preferred Step 1 agents (not labeled as "STEP 2"):**
  - 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

- **Non-preferred agents labeled as "STEP 2":**
    - The member must have failed a 2-week trial of all preferred and non-preferred drug entities within the same potency category and dosage form group within the last 3 months.

Super-High Potency (Group 1)

Dosage Form	Preferred		Non-Preferred	
Cream	clobetasol emollient	0.05%		
	clobetasol propionate	0.05%		
	fluocinonide	0.10%		
	halobetasol propionate	0.05%		
Lotion	clobetasol propionate	0.05%	betamethasone dipropionate, augmented	0.05%
			STEP 2* IMPEKLO (clobetasol)	0.05%
			STEP 2* ULTRAVATE (halobetasol) MDP	0.05%
Ointment	betamethasone dipropionate, augmented	0.05%	halobetasol propionate	0.05%
	clobetasol 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 propionate foam	0.05%
	clobetasol propionate spray	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate gel	0.05%	STEP 2* halobetasol propionate foam	0.05%

High Potency (Group 2)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone dipropionate, augmented	0.05%	STEP 2* APEXICON E (diflorasone emollient)	0.05%
	fluocinonide	0.05%	desoximetasone	0.25%
	HALOG (halcinonide)– *Brand Required*	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	STEP 2* diflorasone diacetate	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	fluocinonide gel	0.05%	desoximetasone gel	0.05%
	fluocinonide solution	0.05%	desoximetasone spray	0.25%
			STEP 2* HALOG (halcinonide) SOLUTION	0.10%

High Potency (Group 3)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone dipropionate emollient	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		Non-Preferred	
Cream	fluticasone propionate	0.05%	STEP2* clocortolone pivalate	0.10%
	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, Solution, Spray	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147 MG/G
			STEP2* SERNIVO (betamethasone) SPRAY	0.05%

Lower-Mid Potency (Group 5)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone valerate	0.10%	fluocinolone acetonide	0.03%
	PANDEL (hydrocortisone probutate)	0.10%	prednicarbate	0.10%
			STEP2* flurandrenolide	0.05%
			hydrocortisone butyrate	0.10%
			hydrocortisone butyrate emollient	0.10%
			hydrocortisone valerate	0.20%
Lotion	betamethasone dipropionate	0.05%	flurandrenolide	0.05%
	triamcinolone acetonide	0.10%	fluticasone propionate	0.05%
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		Non-Preferred	
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, Shampoo, Solution	CAPEX (flucinolone) SHAMPOO	0.01%		
	fluocinolone acetonide oil	0.01%		
	fluocinolone acetonide solution	0.01%		

Least Potent (Group 7)

Dosage Form	Preferred		Non-Preferred	
Cream	hydrocortisone	2.50%		
Lotion	hydrocortisone	2.50%		
Ointment	hydrocortisone	2.50%		
Solution			TEXACORT (hydrocortisone) SOLUTION	2.50%

Endocrinology

Androgens

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of each preferred agent with a comparable route of administration, 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).

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	DEPO-TESTOSTERONE (testosterone cypionate)
	XYOSTED (testosterone enanthate)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JATENZO (testosterone undecanoate)	ANDROID (methyltestosterone)
	methyltestosterone
	METHITEST (methyltestosterone)
	TESTRED (methyltestosterone)

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	ANDROGEL (testosterone)
testosterone 1% (50mg/5g) gel packet	FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP
testosterone 1% (25mg/2.5g) gel packet	TESTIM (testosterone) GEL TUBE
testosterone 1% (25mg/2.5g) gel tube	testosterone 2% (10mg/0.5g) gel MD PMP bottle

testosterone 1% (50mg/5g) gel tube	testosterone 1.62% (20.25mg/1.25g) gel packet
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	testosterone 1.62% (40.5mg/2.5g) gel packet
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	VOGELXO (testosterone)
testosterone 2% (30mg/1.5g) solution MD PMP	

Diabetes

References:

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

Underutilization

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

Therapeutic Duplication

- One Strength of one medication is allowed at a time
- Medication classes not payable together:
  - DPP4-Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP4-Inhibitors should not be used concurrently due to similar mechanisms of action
  - DPP4-Inhibitors and Insulins
    - GLP-1 should be considered in most members prior to insulin
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued
  - 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.

Covered options in combination with Insulin therapy:

GLP-1 Agonists, 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.

DPP4-Inhibitors

Electronic Age Verification

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

Electronic Step Care and Concurrent Medications

- DPP4-Inhibitors require concurrent metformin
  - A total of 56-day supply of metformin must be paid within 100 days prior to the DPP4-Inhibitor's date of service.
    - Metformin is recommended to be continued with escalation of therapy with DPP4-Inhibitors. If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C and are first line alternatives.

- Members with GI intolerances to high dose IR metformin should trial at minimum a dose of 500mg ER.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial with EACH of the following agents, as evidenced by paid claims or pharmacy printouts:
  - A preferred sitagliptin product (Janumet, Janumet XR, or Januvia)
  - A preferred linagliptin preferred product (Jentadueto or Tradjenta)
  - A preferred SGLT2 inhibitor

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

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)	++KOMBIGLYZE XR (saxagliptin/metformin)
TRADJENTA (linagliptin)	++NESINA (alogliptin)
	++ONGLYZA (saxagliptin)
	++OSENI (alogliptin/pioglitazone)

DPP4-Inhibitors/SGLT2 Inhibitors Combination

General Prior Authorization Form

Non-Preferred Agent Criteria:

- The prescriber must provide medical justification explaining why the member cannot use individual preferred products separately

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

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

GLP-1 Agonists

General Prior Authorization Form

Non-Preferred Step 1 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 90-day trials of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.
- The member must meet one of the following criteria:
  - The member must have had a 90-day trial of a combination of a SGLT-2 Inhibitor and a DPP-4 Inhibitor, as evidenced by paid claims or pharmacy printouts
  - The member is using insulin
  - Clinical justification must be provided explaining why the member must use a GLP-1 agonist rather than a DPP-4 Inhibitor (subject to clinical review)

Non-Preferred Step 2 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 90-day trials of each preferred and non-preferred Step 1 agent titrated to max tolerated dose, as evidenced by paid claims or pharmacy printouts.

++Clinically Non-Preferred: Byetta is less effective than other available agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED)	NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED)
VICTOZA (liraglutide)	TRULICITY (dulaglutide)	ADLYXIN (lixisenatide)
		BYDUREON BCISE (exenatide microspheres)
		++BYETTA (exenatide)
		OZEMPIC (semaglutide)
		RYBELSUS (semaglutide)

Gastroparesis

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - Clinical justification must be provided explaining why the member is unable to use an oral dosage formulation (including ODT and solution formulations) with relevant medical documentation (e.g. swallow study) attached to the request, subject to clinical review.
- **Renewal Criteria:** *Approval Duration = 3 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)

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

Glucose Rescue Medications

Electronic Duration Verification

- 2 doses (initial and replacement doses) are covered every 180 days without prior authorization.
  - The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:
    - The provider must attest if it is known that the previous dose was taken by the member (and not diverted or given to another person)
    - One of the following criteria must be met (A, B, or C)
      A. The previous dose has expired
      B. The dose was used by member for a hypoglycemic episode
      C. The member is currently taking insulins or sulfonylureas and meets one of the following criteria:
        - The diabetes treatment has been adjusted to prevent future instances of hypoglycemia
        - The provider has provided medical justification why the diabetes treatment has not been adjusted at this time to prevent future instances of hypoglycemia.

Prior Authorization

General Prior Authorization Form:

Non-Preferred Criteria:

- The member must have had a trial of a Baqsimi or Zegalogue, 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	GVOKE (glucagon) INJECTION
Glucagon Kit – Labeler 00002	Glucagon Kit - 00548
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	GLUCOGEN (glucagon) HYPOKIT

Insulin/GLP-1 Agonist Combination

General Prior Authorization Form

Group Criteria:

- The prescriber must provide medical justification explaining why the member cannot use the individual preferred products separately (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SOLIQUA (Insulin glargine/lixisenatide)
	XULTOPHY (insulin degludec/liraglutide)

Insulin

Electronic Duration Verification

- Products containing NPH insulin are limited to 210 days of coverage for every 365 days to allow for use in pregnancy and breastfeeding.
    - Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.
    - For an override request: please submit clinical justification explaining why the member is unable to use Lantus or Levemir (subject to clinical review) and attach to Insulin Prior Authorization Form

Quantity Limit

- **Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:**
    - Doses between 100 unit/day to 200 unit/day are covered automatically (do not require prior authorization approval for coverage).
        - Please request an override if day supply is less than 30 days and dose is between 100 units/day and 200 units/day by calling 1-800-755-2604 (e.g. short-cycle filling).
    - **For dose <100 unit/day**, member must meet prior authorization criteria
    - **For dose >200 units of insulin per 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 U500 insulin).

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

- **Fiasp:** *Approval 12 months*
    - The member must have had a 3-month trial of one of the following agents, as evidenced by paid claims or pharmacy printouts.
        - Novolog, Humalog, or Apidra
- **Humalog U-200:** *Approval 12 months*
    - 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
    - if insulin requirement is > 200 units/day: clinical justification must be provided why member is not a candidate for Humulin R U-500
    - Request must not be for use in an insulin pump: HUMALOG® (insulin lispro) 200 Units/mL: Do Not Use in a Pump (lillymedical.com)
- **Regular Insulin (Humulin R / Novolin R / Afrezza):** *Approval 12 months*
    - The member must have had a 3-month trial of two of the following agents, as evidenced by paid claims or pharmacy printouts.
        - Novolog, Humalog, or Apidra

++**Clinically Non-Preferred:** ACOG guidelines prefer insulin analogues (insulin aspart and lispro) over regular insulin due to better compliance, better glycemic control, and overall fever hypoglycemic episodes

- ACOG: American College of Obstetricians and Gynecologists

- **Toujeo Solostar and Tresiba:**
  - **Initial Criteria:** *Approval 6 months*
    - The requested agent must be prescribed by or in consultation with an endocrinologist or diabetes specialist.
    - The member has had a 90-day trial with good compliance, as evidenced by paid claims or pharmacy printouts, of each of the following:
      - Lantus
      - Levemir
    - One of the following must be met, as evidenced by provided clinical notes or labs (1 or 2):
      - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
      - The member must be experiencing inconsistent blood sugars
  - **Renewal Criteria:** *Approval 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 (A1C)
- **All other non-preferred insulins:**
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Rapid Acting Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
APIDRA (insulin glulisine) VIAL	ADMELOG (insulin lispro) VIAL
APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	ADMELOG SOLOSTAR (insulin lispro) INSULIN PEN
HUMALOG (insulin lispro) CARTRIDGE	++AFREZZA (insulin regular, human)
HUMALOG U-100 (insulin lispro) KWIKPEN – *Brand Co-Preferred*	FIASP (insulin aspart) CARTRIDGE***
HUMALOG (insulin lispro) VIAL– *Brand Co-Preferred*	FIASP (insulin aspart) SYRINGE***
HUMALOG JUNIOR KWIKPEN (insulin lispro) – *Brand Co-Preferred*	FIASP (insulin aspart) VIAL***
Insulin aspart cartridge	HUMALOG U-200 (insulin lispro) KWIKPEN
Insulin aspart syringe	++HUMULIN R (insulin regular, human) VIAL
Insulin aspart vial	LYUMJEV (Insulin lispro-aabc) KWIKPEN
Insulin lispro junior syringe	LYUMJEV (Insulin lispro-aabc) VIAL
Insulin lispro cartridge	++NOVOLIN R (insulin regular, human) FLEXPEN
Insulin lispro syringe	++NOVOLIN R (insulin regular, human) VIAL
Insulin lispro vial	
NOVOLOG (insulin aspart) CARTRIDGE – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) FLEXPEN – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) VIAL– *Brand Co-Preferred*	
Intermediate Acting Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NOVOLIN N (insulin NPH human isophane) FLEXPEN	HUMULIN N (insulin NPH human isophane) VIAL
HUMULIN R (Insulin regular, human) U-500 KWIKPEN	HUMULIN N (insulin NPH human isophane) KWIKPEN
HUMULIN R U-500 (insulin regular, human) VIAL	NOVOLIN N (insulin NPH human isophane) VIAL
Long Acting Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**

LANTUS (insulin glargine) SOLOSTAR	BASAGLAR KWIKPEN U-100 (insulin glargine)
LANTUS (insulin glargine) VIAL – *Brand Required*	SEMGLEE (insulin glargine)
LEVEMIR (insulin detemir) VIAL	TOUJEO SOLOSTAR (insulin glargine)***
LEVEMIR (insulin detemir) FLEXTOUCH	TRESIBA (insulin degludec) FLEXTOUCH U-100***
TOUJEO MAX SOLOSTAR (insulin glargine)PA***	TRESIBA (insulin degludec) VIAL***
TRESIBA (insulin degludec) FLEXTOUCH U-200 PA***	
Mixed Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN – *Brand Required*	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	
HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	
Insulin aspart protamine/insulin aspart insulin pen	
Insulin aspart protamine/insulin aspart vial	
Insulin lispro mix 75/25 kwikpen	

SGLT2 Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	STEGLATRO (ertugliflozin
INVOKANA (canagliflozin)	STEGLATROMET (ertugliflozin/metformin)
INVOKAMET (canagliflozin)	
INVOKAMET XR (canagliflozin/metformin)	
JARDIANCE (empagliflozin)	
SYNJARDY (empagliflozin/metformin)	
SYNJARDY XR (empagliflozin/metformin)	
XIGDUO XR (dapagliflozin/metformin)	

Sulfonylureas

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of glipizide, 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).

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride	++glyburide
glipizide	++glyburide/metformin
glipizide/metformin	++glyburide, micronized

glipizide ER	++GLYNASE (glyburide, micronized)

Growth Hormone

Prior Authorization Form - Growth Hormone

Category Criteria:

- Members new to GH therapy must meet the criteria below and be started on a preferred growth hormone.
    - Members continuing GH therapy and having met the criteria listed below must be switched to a preferred growth hormone.
- **For Initial or Renewal Requests:**
    - Member must have a diagnosis of a **covered indication** (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
    - For all covered indications:
        - Member must not have active malignancy
        - Prescriber must be an endocrinologist or nephrologist, or prescriber must have at least one annual consultation about the member with the pediatric specialty.
        - Member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
            - Exceptions:
                - Member has a diagnosis of Prader-Willi syndrome
                - Member has a diagnosis of endogenous growth hormone deficiency - and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
                    - Skytrofa is contraindicated in patients with epiphyseal closure
    - Diagnosis of chronic renal insufficiency (additional criteria):
        - Member must not have received a renal transplant.
        - Member must consult with a dietitian to maintain a nutritious diet.
    - Diagnosis of Prader–Willi syndrome (additional criteria):
        - Sleep apnea must be ruled out by sleep study in obese members.
        - Member must consult with a dietitian to maintain a nutritious diet.
- **Additional Criteria for Initial Authorization Requests:**
    - Diagnosis of endogenous growth hormone deficiency:
        - Must meet ONE of below criteria (A OR B)
            A. Members with multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
            B. Member must have had two GH stimulation tests by insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon with a maximum peak of < 10ng/mL after stimulation no more than 6 months apart
- **Additional Criteria for Subsequent Authorization**
    - For all covered indications:
        - Member must have been compliant with growth hormone (last 6 fills must have been on time).

- Diagnosis of Prader–Willi syndrome (additional criteria):
  - If member is obese, BMI must have decreased. If member is not obese, BMI must have maintained or decreased.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
	GENOTROPIN MINIQUICK (somatropin)
	NUTROPIN AQ (somatropin)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (somatropin)
	ZOMACTON (somatropin)

Serostim

Prior Authorization Form - Growth Hormone

Product Specific Criteria (Initial):

- Member must have a diagnosis of treatment of HIV with wasting cachexia
- Member must not have an active malignancy
- Prescriber must be experienced in the diagnosis and management of HIV infection
- Member must be on concomitant antiretroviral therapy
- Member must have failed a 3-month trial with Megace, as evidenced by paid claims or pharmacy Printouts

Product Specific Criteria (Renewal):

- Lean body mass and body weight must have increased in the past 12 weeks
- Physical endurance must have increased in past 12 weeks
- Member must not have completed 48 weeks of continuous treatments

Zorbtive

Prior Authorization Form - Growth Hormone

Product Specific Criteria:

- Member must not have active malignancy
- Member must have diagnosis of short bowel syndrome
- Member must be receiving specialized nutritional support
- Treatment duration must not be longer than 4 weeks

Imcivree

General Prior Authorization Form

- **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), as confirmed by genetic testing attached to the request
  - The member's obesity must be due to one of the following variants interpreted as pathogenic, likely pathogenic, or of unknown significance:
    - proopiomelanocortin (POMC)
    - proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - leptin receptor (LEPR) deficiency
  - The member must be 6 years of age or older
  - The medication is prescribed by, or in consultation with, an endocrinologist or expert in rare genetic disorders of obesity
  - The member's weight and body mass index (BMI) must be provided within the last 60 days
  - The member must not have significant renal impairment (eGFR <60 mL/minute/1.73 m2)

- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must have achieved or maintained a 5% weight reduction or 5% of BMI for members < 18 years old, since starting treatment with Imcivree, as evidenced by medical documentation (e.g. chart notes) attached to the request.

PREFERRED AGENTS (CLINICAL PA REQUIRED)
IMCIVREE (Setmelanotide)

GI - Gastroenterology

Bowel Prep Agents

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 1 month*

- The member must have a diagnosis of an FDA-approved indication for use
- One of the following must be met (A or B):
  - A. The member must have failed a trial of each preferred agent within the past 2 years, as evidenced by paid claims or pharmacy printouts
  - B. Clinical justification must be provided explaining why the member is unable to use the preferred agents, with medical documentation (e.g. chart notes) documenting the reason(s) preferred agents cannot be used (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLENPIQ	GAVILYTE-N
GAVILYTE-C	GOLYTELY 236-22.74G
GAVILYTE-G	NULYTELY
GOLYTELY 227.1-21.5	PEG 3350/SOD SUL/NACL/KCL/ASB/C
MOVIPREP – *Brand Required*	PLENVU
OSMOPREP	SUPREP
PEG-3350 AND ELECTROLYTES 236-22.74G	SUTAB
PEG 3350-ELECTROLYTE 420 G	
TRILYTE	

Crohn's Disease

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Anti – TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	CIMZIA (certolizumab)

Anti – interleukin (IL) 12/IL-23

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

Clostridium difficile-associated diarrhea (CDAD)

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 5 days*

- The member must have diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)
- The member must have failed a 10-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIRVANQ (vancomycin) SOLUTION 25mg/mL	DIFICID (fidaxomicin) 40 MG/ML SUSPENSION
Vancomycin capsule	DIFICID (fidaxomicin) TABLET
Vancomycin solution 50mg/mL	FIRVANQ (vancomycin) SOLUTION 50 MG/ML
	VANCOCIN (vancomycin) CAPSULE

Constipation – Irritable Bowel Syndrome/Opioid Induced

Therapeutic Duplication

- One medication is allowed at a time

Idiopathic Constipation

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of Linzess, as evidenced by paid claims or pharmacy printouts

Product Specific Criteria

- ***Motegrity: The member must have had a 30-day trial with Trulance, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone) - *Brand Required*	LINZESS (linaclotide) 72 mcg
LINZESS (linaclotide) 145 mcg, 290 mcg	lubiprostone
	MOTEGRITY (prucalopride)***
	TRULANCE (plecanatide)

Opioid-Induced Constipation:

Electronic Step Care and Concurrent Medications

- Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.
    - 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

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).

- The member must have had 30-day trials of each of the oral preferred agents, as evidenced by paid claims or pharmacy printouts

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

Diarrhea

Electronic Step Care and Concurrent Medications

- Xifaxan: Xifaxan 550mg 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

Non-Preferred Agents Criteria:

- **Initial Criteria**: *Approval Duration = 3 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis, age, and duration of treatment).
  - The provider must submit medication documentation confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
  - The member must have had a 30-day trial of each preferred unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- **Product Specific Criteria:**
  - ***__alosetron__: The member must be a female.
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must have experienced and maintained clinical benefit since starting treatment with requested product, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review)

Irritable Bowel Syndrome

General Prior Authorization Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dicyclomine capsule	alosetron***
dicyclomine tablet	dicyclomine oral syrup
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron)*** - *Brand Required*	XIFAXAN (rifaximin) 550 mg tablet

HIV/AIDs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	MYTESI (crofelemer)

Digestive Enzymes

General Prior Authorization Form

Non-Preferred Agents Criteria:

- 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

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

Proton Pump Inhibitor

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.

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:
    - **Please call for an override** if any of the following circumstances apply 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

Electronic Age Verification

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

Electronic Step Care and Concurrent Medications

Non-Preferred Agents Criteria - Step 1 Agents:

- A total of 28 days of 2 preferred agents at max dose must be paid within 365 days prior to non-preferred step 1 agents date of service.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria - Step 2 Agents: *Approval Duration = 6 months*

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

Solid Dosage Forms

SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DEXILANT (dexlansoprazole)	esomeprazole magnesium	ACIPHEX (rabeprazole)
lansoprazole	rabeprazole	NEXIUM (esomeprazole)

omeprazole		omeprazole-sodium bicarbonate
pantoprazole		PREVACID (lansoprazole)
		PRILOSEC (omeprazole)
		PROTONIX (pantoprazole)

Non-Solid Dosage Forms

NON-SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)**	**NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)**
NEXIUM (esomeprazole) PACKET *– Brand Required*	PRILOSEC SUSPENSION (omeprazole)	ACIPHEX SPRINKLE (rabeprazole)
omeprazole ODT		esomeprazole solution packet
PREVACID (lansoprazole) SOLUTAB *– Brand Required*		lansoprazole ODT
PROTONIX (pantoprazole) PACKET *– Brand Required*		omeprazole-sodium bicarbonate packet
		pantoprazole packet

Ulcerative Colitis

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of each preferred biologic agent, as evidenced by paid claims or pharmacy printouts.

Biologic Agents

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Anti – TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	SIMPONI (golimumab)

Anti – interleukin (IL) 12/IL-23

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

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ (tofacitinib)	
XELJANZ XR (tofacitinib)	

Sphingosine 1-Phosphate (S1P) Receptor Modulator

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

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO (mesalamine) CAPSULE – *Brand Required*	AZULFIDINE (sulfasalazine)
ASACOL HD (mesalamine) – *Brand Required*	AZULFIDINE DR (sulfasalazine)
balsalazide capsule	COLAZAL (balsalazide)

DELZICOL (mesalamine) CAPSULE– *Brand Required*	mesalamine DR
DIPENTUM (olsalazine)	mesalamine ER
LIALDA (mesalamine) TABLET– *Brand Required*	mesalamine HD
PENTASA (mesalamine)	
sulfasalazine DR tablet	
sulfasalazine tablet	

Rectal

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

Genetic and Rare Disease

Biologics

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age) as follows:

Chronic Infantile Neurological, Cutaneous and Articular Syndrome

Schnitzler Syndrome

Sterile Multifocal Osteomyelitis with Periostitis and Pustulosis

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

Deficiency of IL-A Receptor Antagonists (DIRA)

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

Cytokine release syndrome

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

Phenylketonuria

Kuvan:

Underutilization

- Kuvan must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

Criteria for initial requests: *Approval Duration = 2 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have been compliant with a PHE restricted diet for past 6 months.
- The member must not have been known to have two null mutations in TRANS
- Baseline PHE levels must be attached
    - For females of childbearing potential: PHE levels must be above 360 micromoles/liter
    - For males or females unable to bear children: PHE levels must be above 600 micromoles/liter
- The member's weight must be provided. Requested initial dose must be 10 mg/kg or less.

Criteria for renewal requests: *Approval Duration = 12 months*

- The member's weight must be provided
- If dose is the same or less than previous trial:
    - PHE level must be between 60 and 360 micromoles per liter
- For a dose increase from previous trial:
    - PHE levels must be attached that were taken after 1 month of previous trial
    - The member's PHE level must be greater than 360 micromoles per liter
    - For increase > 10 mg/kg - member must have failed a trial of 1 month of 10 mg/kg

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KUVAN (sapropterin) – *Brand Required*	sapropterin

Palynziq (pegvaliase-pqpz):

Prior Authorization Form - Phenylketonuria

Criteria for initial requests: *Approval Duration = 6 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- PHE levels must be above 600 micromoles/liter
- The member must have been compliant with a PHE restricted diet and medication management for past 6 months.

Criteria for renewal requests: *Approval Duration = 12 months*

- **If dose is the same or less than previous trial:**
    - PHE level must be between 60 and 360 micromoles per liter
- **For a dose increase to 40 mg:**
    - PHE levels must be attached that were taken after 24 weeks of 20 mg
    - The member's PHE level must be greater than 360 micromoles per liter

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PALYNZIQ (pegvaliase-pqpz)	

Hematology/Oncology

Antihemophilic Factor Products

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- Contact information for treatment center must be provided

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the PREFERRED AGENTS (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)

FACTOR VIIa	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	
FACTOR VIII – HEMOPHILIA A	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Non-Extended Half Life	
ADVATE (factor VIII recombinant)	KOVALTRY (factor VIII recombinant)
AFSTYLA (factor VIII recombinant, single chain)	NUWIQ (factor VIII recombinant)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	
KOATE (factor VIII plasma derived, chromatography purified)	
KOGENATE FS (factor VIII recombinant)	
NOVOEIGHT (factor VIII recombinant)	
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	
RECOMBINATE (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	
Extended Half Life	
ESPEROCT (factor VIII recombinant, glycopegylated – exei)	ADYNOVATE (factor VIII recombinant, PEGylated)
	ELOCTATE (factor VIII recombinant, Fc fusion protein)
	JIVI (factor VIII recombinant, pegylated-aucl)
FACTOR VIII:C – HEMOPHILIA A	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
MONOCLATE-P (Antihemophilic Factor VIII:C (human))	
FACTOR VIII – HEMOPHILIA A/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))	
FACTOR VIII – VON WILLEBRAND FACTOR - RECOMBINANT	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	VONVENDI (Recombinant human vWF)
FACTOR IX – HEMOPHILIA B	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Non-Extended Half Life	
ALPHANINE SD (factor IX, plasma-derived)	
BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
MONONINE (factor IX, plasma-derived mAb purified)	
PROFILNINE (factor IX complex)	
RIXUBIS (factor IX recombinant)	
Extended Half Life	
ALPROLIX (factor IX recombinant, Fc fusion)	REBINYN (factor IX recombinant, glycol-PEGylated)
IDELVION (factor IX recombinant, albumin fusion)	
FACTOR IXa/IX	

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (Emicizumab-kxwh)	
FACTOR X	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
COAGADEX (Coagulation Factor X (Human))	
FACTOR X	
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)	
ANTI-INHIBITOR COAGULANT COMPLEX	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
FEIBA NF (Anti-Inhibitor Coagulant Complex)	

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Soliris/Ultomiris: See Medical Billing Drug Clinical Criteria

Empaveli

Empavali - Prior Authorization Form

Initial Criteria: *Approval Duration = 6 months*

- The patient must be 18 years of age or older
- Must be prescribed by or in consultation with a hematologist, oncologist, or immunology specialist
- Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry (LDH level of 1.5 times the upper limit of normal)
- Must have documented have one of the following at least 2 weeks before starting treatment:
    a. A full course of meningococcal, pneumococcal, and Hib vaccines
    b. A test for antibodies against encapsulated bacteria
    c. 2 weeks of antibacterial drug prophylaxis against S. *pneumoniae*, N. *meningitis*, and H. *influenzae* type B if vaccines are administered less than 2 weeks prior to starting therapy
- One of the following criteria must be met (A or B):
    A. Member is transfusion-dependent
    B. Member has hemoglobin ≤ 7 g/dL or Hb ≤ 9 g/dL and member has symptoms of thromboembolic complications (e.g. abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)

Renewal Criteria: *Approval Duration = 12 months*

- Documentation has been submitted that support one of the following positive responses to therapy:
    - Decrease in transfusions from baseline
    - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
    - Normalization in LDH levels ≤ 280 U/L

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

Medical Billing Drug Clinical Criteria Only

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SOLIRIS (eculizumab)	
ULTOMIRIS (ravulizumab)	

Hematopoietic, Colony Stimulating Factors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
	NIVESTYM (filgrastim-AAFI)
	ZARXIO (filgrastim-SNDZ)

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NYVEPRIA (pegfilgrastrim – APGF)	FULPHILA (pegfilgrastrim-JMDB)
ZIEXTENZO (pegfilgrastim-BMEZ)	NEULASTA (pegfilgrastim)
	UDENYCA (pegfligrastim-CBQV)

Sargramostim

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

Nausea/Vomiting

Chemo Induced

Electronic Diagnosis Verification

- **Dronabinol:** The member must have an FDA-approved indication for use

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 6 months or until last day of chemotherapy*

- The member must have diagnosis of nausea and/or vomiting
- Prescriber must be 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
- 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 print outs
- Member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects

NK1 RECEPTOR ANTAGONISTS	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron)	aprepitant Capsule
	EMEND (aprepitant) CAPSULE
	EMEND (aprepitant) SUSPENSION
	VARUBI (rolapitant) TABLET
5-HT3 RECEPTOR ANTAGONISTS	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron)	SANCUSO (granisetron) PATCH
granisetron tablet	ZOFRAN (ondansetron) TABLET

ondansetron ODT	SUSTOL (granisetron) SYRINGE
ondansetron solution	
ondansetron tablet	
CANNABINOIDS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
dronabinol capsule	MARINOL (dronabinol) CAPSULE

Sickle Cell Disease

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria**: *Approval Duration = 12 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis, age, and duration of treatment)
  - The member must have had a 30-day trial of a preferred agent at the maximum (35 mg/kg/day) or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts
  - Prescribed by, or in consultation, with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease
  - Member has experienced at least one sickle cell-related vaso-occlusive crisis within past 12 months (documentation required)
- **Product Specific Criteria:**
  - **Oxbryta:**
    - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - **Siklos:**
    - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
    - 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*
  - 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
    - Member has experienced a reduction in sickle cell-related vaso-occulusive crisis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea capsule)	ENDARI (glutamine)
hydroxyurea capsule	OXBRYTA (voxelotor)
	SIKLOS (hydroxyurea tablet)

Thrombocytopenia

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Product Specific Criteria: Promacta Powder Pack: In addition to diagnosis specific criteria

- Patient must be 9 years old or younger OR unable to swallow a solid dosage form

Persistent or Chronic immune thrombocytopenia (ITP):

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >6 months after diagnosis.
  - 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 print outs OR
    B. Rituximab OR
    C. The member must have undergone a splenectomy
- **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)

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

Chronic liver disease-associated thrombocytopenia

- **Clinical Criteria:** *Approval Duration The 2 weeks prior to procedure*
  - The member must have a diagnosis of chronic liver disease
  - The member must have platelet count of less than 50 x 10^9/L
  - The member must be scheduled to undergo a procedure that puts the member at risk of bleeding
    - The prescriber must include documentation of the name and scheduled date of the procedure
  - The provider must indicate the date therapy will be initiated and discontinued
    - Member must undergo procedure within 8 days after last dose*
      *Doptelet: Member must undergo procedure 5-8 days after last dose
      *Mulpleta: Member must undergo procedure 2-8 days after last dose

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (Avatrombopag)	MULPLETA (Lusutrombopag)

Chronic hepatitis C infection-associated thrombocytopenia

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of hepatitis C-associated thrombocytopenia
  - Prescriber must attest that the member's degree of thrombocytopenia prevents initiation or continuation of interferon-based therapy
  - Member is unable to receive direct acting antivirals for hepatitis C
- **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)
  - Member is currently receiving interferon-based therapy

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

Aplastic Anemia

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of aplastic anemia

- Member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g. corticosteroid, Atgam, cyclosporine, cyclosporine)
- Documentation of platelet count of less than 30 x 10^9/L

- **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)

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

Infectious Disease

Antibiotics - Resistance Prevention

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 5 days*
  - Member must have an FDA-approved indication for use (meets label recommendations for diagnosis & age)
    - Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - Medication must be prescribed by an infection disease specialist, an antibiotic stewardship program, or protocol.
  - One of the following criteria must be met (A or B)
    - A. Prescriber must provide evidence-based medical justification for use, explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
    - B. The member is continuing treatment upon discharge from an acute care facility
- **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).

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	

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	HELIDAC (bismuth ssal/metronidazole/tetracycline)
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline)	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
	PREVPAC (lansoprazole/amoxicillin/clarithromycin)
	TALICIA (omeprazole/amoxicillin/rifabutin)

Tuberculosis

Product specific criteria:

***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.

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

Antifungals - Aspergillus and Candidiasis Infections

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = Per label recommendations*

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- The member must meet one of the following (A or B):
    - The member must have documented history of failure to all preferred agents as evidenced by paid claims or pharmacy printouts
    - Prescriber must provide evidence-based medical justification for use, explaining why preferred antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Solid formulations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clotrimazole	CRESEMBA (isavuconazonium)
clotrimazole troche	DIFLUCAN (fluconazole)
fluconazole	posaconazole
itraconazole	SPORANOX (itraconazole)
NOXAFIL (posaconazole) – *Brand Required*	TOLSURA (itraconazole) CAPSULE
nystatin	VFEND (voriconazole)
ORAVIG (miconazole)	voriconazole
terbinafine	

Non-solid oral formulations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	NOXAFIL (posaconazole) SUSPENSION
	SPORANOX (itraconazole) SOLUTION
	VFEND (voriconazole) SUSPENSION
	voriconazole suspension

Antimalarial Agents

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- The request must be for TREATMENT of malaria (*NOT covered for prophylaxis)*

Non-Preferred Agents Criteria:

- 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

Product specific criteria:

***atovaquone/proguanil 62.5-25 MG

- The member must be less than 18 years old

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)

Human Immunodeficiency Virus (HIV)

Antiretrovirals

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/inline-files/AdultandAdolescentGL.pdf. Accessed (October 9, 2020)

Category Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilprivirine)	
DOVATO (dolutegravir/Lamivudine)	

GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (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)
EDURANT (rilpivirine)	efavirenz/lamivudine/tenofovir
efavirenz	SUSTIVA (efavirenz)
efavirenz/emtricitabine/tenofovir	
JULUCA (dolutegravir/rilpivirine)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
rilpivirine	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
INTELENCE (etravirine) – *Brand Required*	etravirine
nevirapine	
nevirapine ER	

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)	EPIVIR (lamivudine)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPZICOM (abacavir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	TRIZIVIR (abacavir/lamivudine)
DESCOVY (emtricitabine/tenofovir)	TRUVADA (emtricitabine/tenofovir)
EMTRIVA (emtricitabine) CAPSULE – *Brand Required*	VIREAD (tenofovir)
efavirenz/emtricitabine/tenofovir	ZERIT (stavudine) CAPSULE
emtricitabine solution	ZIAGEN (abacavir)
emtricitabine/tenofovir	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
lamivudine	
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)	
NOT RECOMMENDED FOR FIRST LINE USE	
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. **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). **didanosine –** Guidelines do not recommend ddl/3TC or ddl/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddl toxicities (including pancreatitis and peripheral neuropathy). ddl/TDF regimens are not recommended	

due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities. **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)	
abacavir/lamivudine/zidovudine	COMBIVIR (lamivudine/zidovudine)
didanosine	RETROVIR (zidovudine)
lamivudine/zidovudine	VIDEX EC (didanosine)
stavudine	ZERIT (stavudine) CAPSULE
VIDEX (didanosine)	
zidovudine	

Post-Attachment Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TROGARZO (Ibalizumab-uiyk)	

Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	NORVIR (ritonavir)
EVOTAZ (atazanavir/cobicistat)	REYATAZ (atazanavir) CAPSULE
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir)	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir) SOLUTION
fosamprenavir	LEXIVA (fosamprenavir)
INVIRASE (saquinavir)	lopinavir/ritonavir tablet
KALETRA (lopinavir/ritonavir) TABLET – *Brand Required*	
lopinavir/ritonavir solution	
VIRACEPT (nelfinavir)	

Entry Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

Diarrhea

Product Specific Criteria:

*** **Mytesi:** Jump to Criteria

Loss of Appetite

Product Specific Criteria:

*** **Dronabinol:** Jump to Criteria

Wasting Cachexia

Product Specific Criteria:

*** **Serostim:** Jump to Criteria

Hepatitis C Treatments

Electronic Step Care and Concurrent Medications

- A total of 28 days of ribavirin must be billed within the previous 14 days of an Epclusa (and its generic) claim if member has decompensated cirrhosis (Child Pugh B or C).
    - Epclusa (and its generic) requires prior authorization and after prior authorization is approved, Epclusa (and its generic) will continue to reject for prior authorization unless ribavirin is billed first when it is recommended to be used concurrently.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Antivirals

Category Criteria: *Approval duration – based on label recommendations*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must not be receiving a known recreationally used high risk combination of drugs (e.g. "the holy trinity") for the past 6 months.
- Member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.
- Member must not have life expectancy of less than 12 months due to non-liver related comorbid conditions.
- Member and Prescriber attestation forms must be attached to request
- Chronic Hepatitis C must be documented by one of the following:
    - **Liver fibrosis F1 and below**: 2 positive HCV RNA levels at least 6 months apart.
    - **Liver fibrosis F2 and above**: 1 positive HCV RNA test within the last 12 months.

Prescriber may be primary care provider or family practice with the following exceptions:	
Prescriber must be a hepatology, gastroenterology, or infectious disease specialist	• Decompensated cirrhosis (Child's Pugh B or C)
	• Status post solid organ transplantation
	• Known or suspected hepatocellular carcinoma
	• Evidence/suspicion of acute liver injury while on HCV treatment
	• HIV or HBsAg positive
	• Current pregnancy or breastfeeding
Prescriber must be, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)	• Compensated cirrhosis (Child's Pugh A) • For Hep C retreatment after Direct Acting Antivirals

For FIRST TIME treatments with Direct Acting Antivirals:

Must be drug (drugs of abuse by injection) and alcohol free as documented by:	
No history of alcohol use disorder or history of using drugs of abuse by injection	• 1 drug and alcohol test completed within 30 days of the request date

History of alcohol use disorder or history of drugs of abuse by injection	**Currently enrolled or has completed a substance use treatment program within the past 3 months**	• 1 drug and alcohol test completed within 30 days of the request date • Must be receiving treatment from an enrolled addiction medicine/chemical dependency treatment provider - provider/facility name must be provided with the request • Chart notes must be attached regarding assessment of member's readiness for treatment including readiness for abstinence from alcohol use during and after treatment
	<u>Has not</u> completed a substance use treatment program within the past 3 months	• 2 drug and alcohol tests, dated at least 3 months apart, with the most current test completed within 30 days of the request date • Provider must submit chart notes documenting that the member has maintained sobriety for the past year or since last substance use treatment program completion

For <u>RE-TREATMENT</u> after Direct Acting Antivirals:

Reason for retreatment:		
Due to drugs of abuse by injection	• The member is receiving treatment or must have received from an enrolled addiction medicine/chemical dependency treatment (or buprenorphine waived) provider since initial Hepatitis C treatment with Direct Acting Antivirals, and the provider/facility name must be provided with the request. • The member must not be at high risk of relapse from illicit drug use by injection during and after treatment as evidenced by treatment provider notes or risk assessment	
	Liver fibrosis F2 and below	**Liver fibrosis F3 and above**
	• The provider must submit chart notes documenting that the member has abstained from drugs of abuse for the past year • Two drug tests: 1 test completed 6 months (+/- 1 months) prior to request and 1 test within 30 days of the request date	• Two drug tests: 1 test completed 3 months prior to request and 1 test within 30 days of the request date
Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)	**Liver fibrosis F2 and below**	**Liver fibrosis F3 and above**
	• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 180 days, as evidenced by pharmacy claims history.	• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.
Resistance	• <u>FIRST TIME</u> treatment with Direct Acting Antivirals criteria must be met	

<u>Non-Preferred Agents Criteria:</u>

- The member must have had a trial of each preferred treatment options indicated for the member's genotype, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- Epclusa:
  - 200mg-50mg pellet pack: Members that weigh 30 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria
- Mavyret:
  - 50mg-20mg pellet pack: Members that weigh 45 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
MAVYRET (glecaprevir/pibrentasvir)***	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
SOVALDI (sofosbuvir) 200 MG TABLET	ledipasvir/sofosbuvir 90mg/400mg tablet
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	ZEPATIER (elbasvir/grazoprevir)

Ribavirin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ribavirin capsule	
ribavirin tablet	

Influenza

Electronic Age Verification

- Xofluza: The member must be 12 years of age or older

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

Nephrology/Urology

Benign Prostatic Hyperplasia

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have diagnosis of benign prostatic hyperplasia (BPH)
- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	FLOMAX (tamsulosin)
dutasteride	MINIPRESS (prazosin)

finasteride	PROSCAR (finasteride)
prazosin	RAPAFLO (silodosin)
silodosin	sildenafil
tamsulosin	tadalafil
terazosin	

Chronic Kidney Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	
KERENDIA (finerenone)	
TEKTURNA (aliskiren)	

Hematopoietic, Erythropoiesis Stimulating Agents

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	EPOGEN (epoetin alfa)
PROCRIT (epoetin alfa)	MIRCERA (methoxy polyethylene glycol-epoetin beta)
	RETACRIT (epoetin alfa - epbx)

Hyperkalemia (Chronic)

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial criteria**: *Approval Duration = 3 months*
  - The member must be 18 years of age or older.
  - Medication must be prescribed by, or in consultation with, a nephrologist
  - 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
  - One of the following criteria must be met:
    - 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 the medications known to cause hyperkalemia listed below, OR medical justification must be provided explaining why discontinuation of these agents would be clinically inappropriate in this member:
    - angiotensin-converting enzyme inhibitor
    - angiotensin II receptor blocker
    - aldosterone antagonist
    - nonsteroidal anti-inflammatory drugs (NSAIDs)
- **Renewal Criteria**: *Approval Duration = 6 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

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

LOKELMA (Sodium Zirconium Cyclosilicate)	VELTASSA (Patiromer)

Overactive Bladder

Step Care and Concurrent Medications

- Non-Preferred Step 1 Agents: Less expensive urinary antispasmodics must be trialed first
  - A total of 30 days of a preferred agent at max dose must be paid within 90 days prior to step 1 agents date of service.

Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Alpha 1 blockers (alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, tamsulosin) are not allowed with carvedilol or labetalol
  - carvedilol and labetalol are nonselective beta blockers with alpha 1 blocking activity
- Anticholinergic medications (tolterodine, oxybutynin, trospium, solifenacin) are not covered with Acetylcholinesterase Inhibitors. Click here for a full listing of medications included.
  - 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

Prior Authorization Criteria

General Prior Authorization Form

Solid dosage forms

Non-Preferred Step 1 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of 2 preferred agents and 1 non-preferred step 1 agents, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DETROL (tolterodine) – *Brand Required*	MYRBETRIQ (mirabegron)	darifenacin ER
DETROL LA (tolterodine) – *Brand Required*	flavoxate	DITROPAN XL (oxybutynin)
GELNIQUE (oxybutynin)		dutasteride/tamsulosin
oxybutynin ER		FLOMAX (tamsulosin)
oxybutynin tablet		GEMTESA (vibegron)
OXYTROL (oxybutynin) PATCH		JALYN (dutasteride/tamsulosin)
solifenacin		tolterodine
tamsulosin		tolterodine ER
TOVIAZ (fesoterodine)		trospium ER
trospium		VESICARE (solifenacin)

Non-solid dosage form

Non-Preferred Agents Criteria:

- The member must be 9 years old or younger or provide documentation of inability to swallow.
- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxybutynin syrup	MYRBETRIQ (mirabegron) SUSPENSION

	VESICARE (solifenacin) LS SUSPENSION

Phosphate Binders

General Prior Authorization Form

Category Criteria:

- The member must have had 30-day trials of all preferred agents of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- The member must have a diagnosis of end-stage renal disease or chronic kidney disease.
- If member is on renal dialysis, Medicare eligibility must be ruled out.

Solid dosage form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Calcium acetate	AURYXIA (ferric citrate) TABLET
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	Lanthanum chew tab
Sevelamer Carbonate Tablet	RENAGEL (Sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	Sevelamer HCl 400mg Tablet
	Sevelamer HCl 800mg Tablet
	VELPHORO (Sucroferric oxyhydroxide)

Non-solid dosage form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PHOSLYRA (calcium acetate) ORAL solution	FOSRENOL (lanthanum) POWDER PACK
RENVELA (sevelamer) POWDER PACK – *Brand Required*	Sevelamer Powder Pack

Neurology

Alzheimer's Disease

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors **(**Aricept, Exelon, Razadyne, pyridostigmine). Click here for a full listing of medications included.
  - 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:** Members must have an FDA or compendia supported indication

Electronic Age Verification

- Members must be greater than 30 years old

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Product Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- The member must have had 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 with skilled nursing care.

Product Specific Criteria:

- Donepezil 23mg:
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Cholinesterase Inhibitors	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
donepezil 5mg, 10mg Tablet	ARICEPT (donepezil)
EXELON (rivastigmine) PATCH – *Brand Required*	donepezil ODT
galantamine Tablet	donepezil 23mg tablet
galantamine ER	galantamine oral solution
rivastigmine capsule	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)
	rivastigmine patch
NMDA Receptor Antagonists	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
memantine	memantine oral solution
	memantine ER
	NAMENDA (memantine)
	NAMENDA XR (memantine)
Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NAMZARIC (memantine/donepezil)	

Anticonvulsants

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:
    - All of member's medications dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Electronic Diagnosis Verification

- Diacomit, Epidiolex, Fentepla: The member must have an FDA approved diagnosis

Electronic Step Care and Concurrent Medications

- Diacomit is FDA approved to be used in combination with clobazam.
  - A total of 28 days of clobazam must be paid within 45 days prior to Diacomit (stiripentol)

Prior Authorization Criteria

Group Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of 2 pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Anticonvulsant Prevention

Carbamazepine Derivatives	
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*	oxcarbazepine oral solution
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine)
oxcarbazepine tablet	TEGRETOL (carbamazepine oral suspension)
OXTELLAR XR (oxcarbazepine)	
TRILEPTAL (oxcarbazepine) – *Brand Co-Preferred*	
TRILEPTAL (oxcarbazepine) ORAL SUSPENSION – *Brand Required*	
TEGRETOL XR (carbamazepine) – *Brand Required*	
First Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**
CELONTIN (methsuximide)	DEPAKENE (valproic acid) CAPSULE
clobazam	DEPAKENE (valproic acid) ORAL SOLUTION
clobazam oral solution	DEPAKOTE (divalproex sodium) TABLET
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	
divalproex ER	DEPAKOTE ER (divalproex sodium)
divalproex sprinkle	
divalproex tablet	DILANTIN (phenytoin) CHEWABLE TABLET
ethosuximide capsule	DILANTIN (phenytoin) ORAL SUSPENSION
ethosuximide oral solution	DILANTIN ER (phenytoin)
FELBATOL (felbamate) TABLET– *Brand Required*	felbamate oral suspension
FELBATOL (felbamate) ORAL SUSPENSION - *Brand Required*	felbamate tablet
PEGANONE (ethotoin)	MYSOLINE (primidone)
phenobarbital elixir	ONFI (clobazam)
phenobarbital tablet	ONFI (clobazam) ORAL SOLUTION
phenytoin chewable tablet	PHENYTEK (phenytoin)
phenytoin ER capsule	SYMPAZAN (clobazam)
phenytoin suspension	ZARONTIN (ethosuximide)
primidone	ZARONTIN (ethosuximide) ORAL SOLUTION
valproic acid capsule	
valproic acid oral solution	
Second Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Required*	ELEPSIA XR (levetiracetam)
BANZEL (rufinamide) TABLET – *Brand Required*	KEPPRA (levetiracetam)
BRIVIACT (brivaracetam)	KEPPRA (levetiracetam) ORAL SOLUTION
DIACOMIT (stiripentol)	KEPPRA XR (levetiracetam)
EPIDIOLEX (cannabidiol)	LAMICTAL (lamotrigine)
FINTEPLA (fenfluramine) ORAL SOLUTION	LAMICTAL (lamotrigine) DOSE PACK
FYCOMPA (perampanel)	lamotrigine ODT
FYCOMPA (perampanel) ORAL SUSPENSION	lamotrigine ODT dose pack
gabapentin capsule	lamotrigine chewable tablet
gabapentin oral solution	lamotrigine ER
gabapentin tablet	LYRICA (pregabalin)
GABITRIL (tiagabine) - *Brand Required*	LYRICA (pregabalin) ORAL SOLUTION
LAMICTAL ODT (lamotrigine) DOSE PACK- *Brand Required*	NEURONTIN (gabapentin) CAPSULE
LAMICTAL ER (lamotrigine) DOSE PACK	NEURONTIN (gabapentin) ORAL SOLUTION
LAMICTAL XR (lamotrigine) - *Brand Required*	NEURONTIN (gabapentin) TABLET
LAMICTAL (lamotrigine) CHEWABLE TABLET- *Brand Required*	rufinamide tablet
LAMICTAL ODT (lamotrigine) - *Brand Required*	rufinamide suspension
lamotrigine dose pack	SPRITAM (levetiracetam)
lamotrigine tablet	SUBVENITE (lamotrigine)
levetiracetam ER	tiagabine
levetiracetam oral solution	TOPAMAX (topiramate)

levetiracetam tablet	TOPAMAX (topiramate) SPRINKLE CAPSULE
QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Co-Preferred*	topiramate ER sprinkle cap – Labeler 00245
pregabalin	VIGADRONE (vigabatrin)
pregabalin oral solution	vigabatrin
SABRIL (vigabatrin) - *Brand Required*	vigabatrin powder pack
SABRIL (vigabatrin) POWDER PACK - *Brand Required*	ZONEGRAN (zonisamide)
topiramate ER sprinkle cap – Labeler 00832	
topiramate ER	
topiramate sprinkle capsule	
topiramate tablet	
TROKENDI XR (topiramate)	
XCOPRI (cenobamate)	
zonisamide	
Third Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**
APTIOM (eslicarbazepine)	
VIMPAT (lacosamide)	
VIMPAT (lacosamide) ORAL SOLUTION	

Anticonvulsant treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED):
DIASTAT PEDIATRIC (diazepam) RECTAL GEL – *Brand Required*	diazepam pediatric rectal gel
DIASTAT ACUDIAL (diazepam) RECTAL GEL – *Brand Required*	diazepam rectal gel
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

Emflaza

Prior Authorization Form - Emflaza

Initial Criteria: *Approval Duration = 6 months*

- The member must be 2 years of age or older
- The member must have diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- Onset of weakness must have occurred before 2 years of age
- The medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 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 due to inadequate treatment response, intolerance, or contraindication, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
    i. 6-minute walk test (6MWT)
    ii. North Star Ambulatory Assessment (NSAA)
    iii. Motor Function Measure (MFM)
    iv. Hammersmith Functional Motor Scale (HFMS)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    iv. Diabetes and/or hypertension that is difficult to manage
    v. Severe behavioral adverse effect

Renewal Criteria: *Approval Duration = 12 months*

- The member must have ONE of the following (A or B)
    - Improvement in motor milestone score from baseline from ONE the following assessments:
        i. 6MWT – improvement of 20 meters from baseline
        ii. NSAA – improvement of 2 points from baseline
        iii. MFM – improvement of 2 points from baseline
        iv. HFMS – improvement of 2 points 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. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
        iv. Diabetes and/or hypertension that is difficult to manage
        v. Severe behavioral adverse effect

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Prednisone	EMFLAZA (deflazacort)

Fabry Disease

General Prior Authorization Form

Fabrazyme: See Medical Billing Drug Clinical Criteria

Initial Criteria: *Approval Duration = 6 months*

- The member must have a diagnosis of Fabry disease
- The member must be 18 years of age or older
- 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GALAFOLD (migalastat)

Headache/Migraine

Vyepti – See Medical Billing Drug Clinical Criteria

Prophylaxis of Migraine – CGRP Inhibitors

Prior Authorization Form –Migraine/Cluster Headache Prophylaxis

Group Criteria:

Initial PA Criteria: *Approval Duration: 3 months*

- Member must experience 3 or more migraine days per month.
- The member must have had 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, divalproex sodium, metoprolol, nadolol, propranolol, timolol, topiramate, venlafaxine
- Prescriber must submit documentation, including clinical notes regarding failure of prior treatments to reduce migraine frequency after 2-month trial.

Non-Preferred Agents Criteria:

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

Renewal PA Criteria: *Approval Duration: 12 months*

- The member must have experienced at least a 50% reduction in migraines from baseline, since starting treatment with a CGRP inhibitor.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm)	AIMOVIG (erenumab-aooe)
EMGALITY (galcanazumab-gnlm)	NURTEC ODT (rimegepant)
	QULIPTA (atogepant)

Treatment of Migraine

Therapeutic Duplication

- One strength of one medication is allowed at a time

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- Within the past 2 years, the member must have had 30-day trials of two triptans (5HT-1 agonists), as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents:

- Within the past 2 years, the member must have had a 30-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Triptan Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	REYVOW (lasmiditan)
	UBRELVY (ubrogepant)
Ergot Alkaloids	
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

Triptans (5HT-1 agonists)

Approval Duration = 6 months

Solid Oral Dosage Forms

Non-Preferred Step 1 Agents Criteria:

- Members 18 years old or older: The member must have had a 30-day trial of rizatriptan and Relpax (eletriptan), as evidenced by paid claims or pharmacy printouts.
- Members 6 to 17 years of age: The member must have had a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.

Non-preferred step 2 agents:

- The member must have had either a 30-day trial of each available preferred triptan agent, as evidenced by paid claims or pharmacy printouts or provide clinical justification explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
FROVA (frovatriptan) TABLET– *Brand Required*	naratriptan tablet	almotriptan tablet
RELPAX (eletriptan) TABLET – *Brand Required*	zolmitriptan tablet	AMERGE (naratriptan) TABLET
rizatriptan tablet		eletriptan tablet
sumatriptan tablet		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

Non-Solid Oral Dosage Forms

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Rizatriptan ODT	MAXALT MLT (rizatriptan)
ZOMIG ODT (zolmitriptan) – *Brand Required*	zolmitriptan ODT

Non-Oral Dosage Forms

All (Preferred and Non-Preferred) Non-Oral Dosage Form Agents:

- Members must not able to take oral medications (subject to clinical review).

Product Specific Criteria

- Onzetra Xsail: Member must have had a 30-day trial of zolmitriptan, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- Member must have had a 30-day trial of zolmitriptan and Imitrex (sumatriptan), as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) CARTRIDGE – *Brand Required*	sumatriptan cartridge
IMITREX (sumatriptan) PEN INJCTR – *Brand Required*	sumatriptan pen injctr
IMITREX (sumatriptan) SPRAY – *Brand Required*	sumatriptan spray
IMITREX (sumatriptan) SYRINGE – *Brand Required*	sumatriptan syringe
zolmitriptan spray	sumatriptan vial
ONZETRA XSAIL (sumatriptan) NASAL SPRAY^{PA}***	TOSYMRA (sumatriptan) NASAL SPRAY
	ZEMBRACE SYMTOUCH (sumatriptan)
	ZOMIG (zolmitriptan) NASAL SPRAY

Cluster Headache

Initial PA Criteria: *Approval Duration: 3 months*

- Member must meet ICHD-3 criteria for diagnosis of cluster headache:
    - Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (during active time course)
    - Either or both of the following:
        - At least one 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
        - A sense of restlessness or agitation
    - Occurring with a frequency between one every other day and 8 per day (during active time course)

Cluster Headache Prevention

Non-preferred agents:

- Member must use medication 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 medication is not indicated for chronic use
- Member must have had a 2-month trial with verapamil

Renewal PA Criteria: *Approval Duration: 12 months*

- Prescriber must submit documentation indicating that the members' cluster headaches have been reduced in frequency and/or severity as a result of therapy per member headache journal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
topiramate	EMGALITY (galcanazumab-gnlm)
verapamil	

Cluster Headache Treatment

Non-preferred agents:

- The member must have had a 30-day trial of two unique pharmaceutical preferred agents within the past 24 months, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONZETRA XSAIL (sumatriptan) NASAL SPRAY	D.H.E.45 (dihydroergotamine) INJECTION
IMITREX (sumatriptan) CARTRIDGE – *Brand Required*	Dihydroergotamine (DHE) intranasal
IMITREX (sumatriptan) PEN INJCTR – *Brand Required*	Dihydroergotamine Injection
IMITREX (sumatriptan) SPRAY – *Brand Required*	Dihydroergotamine Nasal Spray
IMITREX (sumatriptan) SYRINGE – *Brand Required*	ERGOMAR (ergotamine) SL TABLET
zolmitriptan oral	IMITREX (sumatriptan) VIAL
zolmitriptan ODT	MIGRANAL (dihydroergotamine) SPRAY
zolmitriptan spray	Sumatriptan Cartridge
	Sumatriptan intranasal
	Sumatriptan Pen Injctr
	Sumatriptan Spray
	Sumatriptan subcutaneous
	Sumatriptan Syringe
	Sumatriptan Vial
	TOSYMRA (Sumatriptan) NASAL SPRAY
	ZEMBRANCE SYMTOUCH (Sumatriptan)

	ZOMIG (Zolmitriptan) NASAL SPRAY

Huntington's Disease

General Prior Authorization Form

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have a diagnosis of an FDA-approved indication for use
  - The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).

  Non-Preferred Agents Criteria:
  - The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts
- **Renewal Criteria:** *Approval Duration = 12 months*
  - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tetrabenazine	AUSTEDO (deutetrabenazine)

Multiple Sclerosis

Injectable Agents

Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of at least 1 preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	PLEGRIDY (peginterferon beta-1A) PEN
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) SYRINGE
BETASERON (interferon beta-1B)	
REBIF (interferon beta-1A)	
REBIF REBIDOSE (interferon beta-1A)	

Injectable Non-Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have had either a 30-day trial of each available preferred multiple sclerosis agent, as evidenced by paid claims or pharmacy printouts or provide clinical justification explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20mg/ml
	glatiramer 40mg/ml
	GLATOPA (glatiramer)

Monoclonal Antibodies

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

Oral Agents

Fumerates

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TECFIDERA (dimethyl fumarate) – *Brand Required*	BAFIERTAM (monomethyl fumarate)
	dimethyl fumarate
	VUMERITY (diroximel fumarate)

Sphingosine 1-Phosphate (S1P) Receptor Modulators

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GILENYA (fingolimod)	MAYZENT (siponimod)
	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

Pyrimidine Synthesis Inhibitor

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of Kesimpta, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUBAGIO (teriflunomide)	MAVENCLAD (cladribine)

Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

Therapeutic Duplication

- Sunosi and Wakix are not allowed together
- Provigil and Nuvigil are not allowed together
- Xyrem, Xywav is not allowed with sleeping medication or benzodiazepines

Electronic Step Care and Concurrent Medications

- Sunosi and Xyrem requires a 30-day trial of armodafinil to be paid within 60 days of submitted claim
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Underutilization

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

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria-

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- 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
- Provider must submit documentation of prior treatment failure, 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

Product Specific Criteria:

- Xywav:
  - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).
  - The member must have had a 30-day trial with Wakix in addition to Non-Preferred Agents Criteria

Renewal Criteria:

- 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	NUVIGIL (armodafinil)
modafinil	PROVIGIL (modafinil)
SUNOSI (solriamfetol)	WAKIX (pitolisant)
XYREM (sodium oxybate)	XYWAV (sodium, calcium, magnesium, potassium oxybate)

Nuedexta (dextromethorphan/quinidine)

Prior Authorization Form - Nuedexta

Group Criteria (Initial): *Approval Duration = 3 months*

- The member must be 18 years of age or older
- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block
- The prescriber must provide the following information:
  - 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
- **Additional initial criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:**
  - 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 classes listed below (A and B), as evidenced by paid claims or pharmacy print outs:
    A. **SSRIs**: sertraline, fluoxetine, citalopram and paroxetine

B. **Tricyclic Antidepressants**: nortriptyline and amitriptyline

- A PBA episode count and CNS-LS score must be provided for before and after each trial

***A failure is defined as one of the following:*

- *PBA count decreased less than 75 percent, stayed the same, or increased from baseline in each trial*
- *CHS-LS score decreased less than 7 points, stayed the same, or increased from baseline in each trial*

Group Criteria (Renewal): *Approval Duration = 6 months*

- Benefit of continued therapy must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode must be reduced by at least 75% from baseline
- **Additional initial criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:**
  - Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
  - Current CNS-LS score must be reduced by at least 30% from baseline

Parkinson's disease

Electronic Step Care and Concurrent Medications

- Xadago and Nourianz is FDA approved for adjunctive treatment to levodopa/carbidopa.
  - A total of 28 days of levodopa/carbidopa treatment must be paid within 40 days prior to Xadago or Nourianz's date of service

Prior Authorization Criteria

General Prior Authorization Form

Parkinson's Agents – Adenosine Receptor Agonist

- **Non-Preferred Agents Criteria (Initial):**
  - The member must have a diagnosis of an FDA-approved indication for use
  - Medication must be prescribed by, or in consultation with, a neurologist
  - Documentation for deterioration in quality of response to levodopa/carbidopa therapy, including currently experiencing intermittent hypomobility, or "off" episodes (number and frequency) must be provided
  - The member must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts
- **Non-Preferred Agents Criteria (Renewal):**
  - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOURIANZ (Istradefylline)	

Parkinson's Agents –Dopaminergic Agents for Intermittent Treatment of Off Episode

- **Group Criteria**
  - The member must have a diagnosis of an FDA-approved indication for use
  - Medication must be prescribed by, or in consultation 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 of intermittent hypomobility or off episodes (number and frequency) must be provided
  - At least one of the following criteria must be met (A and/or B):
    A. Member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response

B. 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)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Subcutaneous	
APOKYN (apomorphine)	
Enteral Suspension	
DUOPA (levodopa/carbidopa)	
Inhalation	
INBRIJA (levodopa)	
Sublingual	
KYNMOBI (apomorphine)	

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

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- The member is must not currently be residing in a facility with skilled nursing care
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

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)
Maintenance - Topical	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPRO (Rotigotine) PATCH	

Parkinson's Agents –Dopamine Precursor

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone	carbidopa-levodopa ODT
carbidopa-levodopa	RYTARY (carbidopa-levodopa)
carbidopa-levodopa ER	SINEMET (carbidopa-levodopa)
	STALEVO (carbidopa-levodopa-entacapone)

Parkinson's Agents –MAO-B Inhibitors

Non-Preferred Agents Criteria

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

Product Specific Criteria:

- ***Xadago:**
  - The member must have a diagnosis of an FDA-approved indication for use

- Medication must be prescribed by, or in consultation 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZILECT (Rasagiline) – *Brand Required*	EMSAM (Selegiline) PATCH
Selegiline	Rasagiline
ZALAPAR ODT (selegiline)	XADAGO (Safinamide)***

Parkinson's Agents – COMT inhibitor

- **Non-Preferred Agents Criteria**
  - The member must have failed a 30-day trial of entacapone, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)
	ONGENTYS (opicapone)
	TASMAR (tolcapone)
	Tolcapone

Parkinson's Agents – Other

- **Non-Preferred Agents Criteria**
  - The member must have a diagnosis of an FDA-approved indication for use
  - The member is must not currently be residing in a facility with skilled nursing care
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
	GOCOVRI (amantadine ER)
	OSMOLEX ER (amantadine ER)

Parkinson's Agents –Ergot Dopamine Receptor Agonists

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

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

Spinal Muscular Atrophy (SMA)

Zolgensma / Spinraza: See Medical Billing Drug Clinical Criteria

Evrysdi

Evrysdi Prior Authorization Form

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have a diagnosis of spinal muscular atrophy (SMA) with the following (as evidenced with submitted documentation):
    - 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 (A and/or B):
      A. Member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
      B. Member is symptomatic (e.g. loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
  - The medication must be prescribed by or in consultation with a neuromuscular neurologist or neuromuscular physiatrist
  - The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
  - The member must be 2 months of age or older
  - The member must not require continuous intubation > 3 weeks
  - The member must not be receiving/have received treatment with Zolgensma
  - The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
  - The provider must submit documentation of the member's current motor function, as evidenced by scores from at least two of the following assessments
    A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
    B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
    C. Hammersmith Functional Motor Scale Expanded (HFMSE)
    D. Motor Function Measure – 32 items (MFM-32)
    E. Revised Upper Limb Module (RULM)
    F. 6 minute walk test (6MWT)
    G. Forced Vital Capacity (FVC) via Pulmonary Function Test

- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
  - The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
  - The member must not require continuous intubation > 3 weeks
    A. The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment with Evrysdi, as evidenced by documentation of current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test, CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores showing maintenance of baseline motor function or significant slowed rate of decline (vs expected natural course of the disease).

PA REQUIRED
EVRYSDI (Risdiplam)

Tardive Dyskinesia

Electronic Step Care and Concurrent Medications

- Start Ingrezza with Initiation Pack before continuing therapy with 80mg capsules

- The 30-count 40 mg bottle is not packaged for titration to 80 mg. If therapy is expected to be continued at 40 mg at time of drug initiation, please call for override.

Prior Authorization

Prior Authorization Form – Tardive Dyskinesia

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
  - The member must have a diagnosis of tardive dyskinesia, including the following:
    - Involuntary athetoid or choreiform movements
    - History of treatment with dopamine receptor blocking agent (DRBA)
    - Symptom duration lasting longer than 4-8 weeks
- **Renewal Criteria:** *Approval Duration = 12 months*
  - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	
INGREZZA (valbenazine)	
tetrabenazine	

Ophthalmology

Antihistamines

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALOCRIL (nedocromil)	bepotastine
ALOMIDE (lodoxamide)	epinastine
azelastine	olopatadine 0.2%
BEPREVE (bepotastine) – *Brand Required*	ZERVIATE (cetirizine)
cromolyn	
LASTACAFT (alcaftadine)	
olopatadine 0.1%	
PAZEO (olopatadine)	

Anti-infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 3-day trials of at least 3 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

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

BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	BLEPH-10 (sulfacetamide) DROPS
gentamicin sulfate drops	CILOXAN (ciprofloxacin) DROPS
moxifloxacin drops	gatifloxacin drops
neomycin SU/polymyxin B/gramicidin drops	levofloxacin drops
ofloxacin drops	MOXEZA (moxifloxacin) DROPS
polymyxin B/trimethoprim drops	NEOSPORIN (neomycin SU/polymyxin B/gramicidin) DROPS
sulfacetamide drops	OCUFLOX (ofloxacin) DROPS
tobramycin drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
	TOBREX (tobramycin) DROPS
	VIGAMOX (moxifloxacin) DROPS
	ZYMAXID (gatifloxacin) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
gentamicin sulfate ointment	
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

Anti-infectives/Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 7-day trials of at least 2 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
neomycin/polymyxin b/dexamethasone drops	neomycin/polymyxin b/hydrocortisone drops
PRED-G (gentamicin/prednisol ac) DROPS	TOBRADEX ST (tobramycin/dexamethasone) DROPS
sulfacetamide/prednisolone drops	tobramycin/dexamethasone drops
TOBRADEX (tobramycin/dexamethasone) DROPS – *Brand Required*	
ZYLET (tobramycin/lotepred etab) DROPS	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	BLEPHAMIDE S.O.P. (sulfacetamide/prednisolone) ointment
PRED-G (gentamicin/prednisol ac) 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

Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 5-day trials of at least 2 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

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

ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
ALREX (loteprednol) DROPS	ACULAR LS (ketorolac) DROPS
diclofenac sodium drops	bromfenac sodium drops
DUREZOL (difluprednate) DROPS – *Brand Required*	BROMSITE (bromfenac sodium) DROPS
FLAREX (fluorometholone) DROPS	dexamethasone sodium phosphate drops
fluorometholone drops	difluprednate drops
flurbiprofen sodium drops	EYSUVIS (loteprednol) DROPS
FML FORTE (fluorometholone) DROPS	INVELTYS (loteprednol) DROPS
ILEVRO (nepafenac) DROPS	FML (fluorometholone) DROPS
ketorolac tromethamine 0.4% drops	LOTEMAX SM (loteprednol) DROPS
ketorolac tromethamine 0.5% drops	loteprednol eye drops
LOTEMAX (loteprednol) DROPS – *Brand Required*	loteprednol gel eye drops
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	PRED FORTE 1% (prednisolone acetate) DROPS
MAXIDEX (dexamethasone) DROPS	PROLENSA (bromfenac) DROPS
NEVANAC (nepafenac) DROPS	
PRED MILD 0.12% (prednisolone acetate) DROPS	
prednisolone acetate 1% drops	
prednisolone sodium phosphate 1% drops	

Ointment

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

Dry Eye Syndrome

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 14-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Cequa, Restasis Multidose, Tyrvaya**
  - The member must have had a 30-day trials of Xiidra, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RESTASIS (cyclosporine)	CEQUA (cyclosporine)***
	RESTASIS MULTIDOSE (cyclosporine)***
	TYRVAYA (varenicline) NASAL SPRAY***
	XIIDRA (lifitegrast)

Glaucoma

Alpha Adrenergic

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS	brimonidine 0.15% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	
apraclonidine 0.5% drops	
brimonidine 0.2% drops	
COMBIGAN (brimonidine/timolol) DROPS	
IOPIDINE (apraclonidine) 1% DROPS	
LUMIFY (brimonidine) 0.03% DROPS	
SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of at least 2 preferred ophthalmic beta blocker products of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

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	COSOPT (dorzolamide/timolol) PF DROPS
dorzolamide/timolol drops	ISTALOL (timolol maleate) DROPS ONCE DAILY
levobunolol drops	timolol drops once daily
timolol maleate drops	timolol gel forming solution
timolol maleate/PF drops	TIMOPTIC (timolol maleate) DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) PF DROPS	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
	TIMOPTIC-XE (timolol gel forming solution)

Prostaglandins

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of at least 2 preferred ophthalmic prostaglandin products of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	travoprost
ROCKLATAN (netarsudil/Latanoprost)	VYZULTA (latanoprostene)
TRAVATAN Z (travoprost) - *Brand Required*	XALATAN (latanoprost)
ZIOPTAN (tafluprost)	XELPROS (latanoprost)

Other

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)

PHOSPHOLINE (Echothiophate Iodide)	ISOPTO CARPINE (pilocarbine)
pilocarpine	TRUSOPT (dorzolamide)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	
SIMBRINZA (brinzolamide/brimonidine)	

Uveitis

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

Otic

Anti-infectives/Anti-inflammatories – Fluoroquinolones

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 7-day trial of one preferred product in the past 3 months, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin/dexamethasone otic drops
CIPRODEX (ciprofloxacin/dexamethasone) – *Brand Required*	ciprofloxacin/fluocinolone
	OTOVEL (ciprofloxacin/fluocinolone)

Pain

Lidocaine patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 4% patch	lidocaine 5% patch
LIDODERM (lidocaine) 5% PATCH – *Brand Required*	
ZTLIDO (lidocaine) 1.8% PATCH	

Lidocaine topical cream

General Prior Authorization Form

Group Criteria:

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)
    - **Please call for an override** if all the following circumstances apply by calling provider relations at 1-800-755-2604:
        - Member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

Electronic Diagnosis Verification

- **Mefenamic acid and Meclofenamate:** The member must have diagnosis of dysmenorrhea or endometriosis

Solid Oral Dosage Forms

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor with GI intolerances, as evidenced by paid claims or pharmacy print outs

Product Specific Criteria:

- **Branded NSAIDs and non-preferred strengths**:
  - Clinical justification must be provided explaining why the member is unable to use other NSAID agents (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib 50mg, 100mg, 200mg	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium	celecoxib 400mg
diclofenac sodium 50mg, 75mg	CELEBREX (celecoxib)
etodolac	CONSENSI (amlodipine/celecoxib)
flurbiprofen	DAYPRO (oxaprozin)
ibuprofen	diclofenac sodium ER 100mg
indomethacin	diclofenac sodium 35mg capsule, submicronized
indomethacin ER	diclofenac/misoprostol
ketorolac	DUEXIS (famotidine/ibuprofen)
meclofenamate	etodolac ER
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	INDOCIN (indomethacin)
naproxen	ketoprofen
piroxicam	ketoprofen ER 200mg
sulindac	meloxicam, submicronized
VIMOVO (naproxen/esomeprazole) – *Brand Required*	MOBIC (meloxicam)
ZIPSOR (diclofenac)	NALFON (fenoprofen)
	NAPRELAN (naproxen)
	naproxen ER 375 mg, 500mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	tolmetin 200mg
	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

Non-Solid Oral Dosage Forms

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ibuprofen suspension	INDOCIN (Indomethacin) SOLUTION

naproxen suspension	

Nasal

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of 2 oral and 1 topical preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	Ketorolac Nasal Spray
	SPRIX (Ketorolac) NASAL SPRAY

Topical:

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials 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 products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Diclofenac 1.5% Topical Solution	Diclofenac Patch
FLECTOR (diclofenac) PATCH - *Brand Required*	LICART (Diclofenac) PATCH 1.3%
PENNSAID (Diclofenac) 2% PUMP	

Opioid Analgesics – Long Acting

Therapeutic Duplication

- Opioids are not allowed with Benzodiazepines: 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
    - **Opioids and Benzodiazepines Override Criteria:**
        - The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports.
        - The member has access to Narcan and has been counseled on overdose risk
        - One of the following criteria must be met:
            - Prescriber must be or be in consult with an oncologist, palliative care specialist, or pain management specialist including a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens)
            - Member must have taper plan of one or both agents
        - The following criteria is met:
            - 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)
            - Prescriber(s) from both the opioid and benzodiazepine attest to the following:

- The member must have 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.
- Opioid dose does not exceed 90 MME/day
- The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)

- Opioids are not allowed with Opioid Use Disorder medications:
  - **Opioid use disorder medications override criteria**:
    Call provider relations at 1-800-755-2604 if all the following circumstances apply:
    - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)
    - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
    - Opioid duration is of a one-time occurrence or taper plan is provided
- Morphine is not covered with Clopidogrel, Prasugrel, Ticagrelor, and Ticlopidine. 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).
- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Nucynta and Nucynta ER are not allowed with other narcotic medications
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Tramadol immediate release with tramadol extended release
- 3A4 Substrates (Fentanyl, methadone, and oxycodone) are not allowed with strong 3A4 inhibitors. Click here for a full listing of medications included.
- Methadone: Not allowed with opioids, benzodiazepines, or opioid use disorder medications
- 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.

Underutilization

- Long-acting opioid analgesics must be used compliantly and will reject on point of sale for late fill

Morphine Milligram Equivalents (MME)

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization
- Member must meet Prior Authorization Criteria
- An MME calculator may be found at Opioid Dose Calculator

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Category Criteria (initial):

- The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports.
- 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.).

- The member must have established opioid tolerability by using short acting opioids daily for at least 90 days prior to request for long-acting opioid as evidenced by paid claims or pharmacy printouts or have exceeded 90 MME during hospitalization requiring post discharge maintenance or tapering.
- The member must have access to Narcan and be counseled on overdose risk or reside in a skilled nursing facility.
- The prescription must be written by or in consultation with an oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if the cumulative daily dose of opioids exceeds 90 MED/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).

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).

Category Criteria (renewal):

- Documentation noting progress toward therapeutic goal must be included with request (including pain level and function).

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 Agonist Opioids

Prior Authorization Form – Opioid Analgesics

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

Full Agonist Opioids Without Abuse Deterrent Formulations

Prior Authorization Form – Opioid Analgesics

Product Specific Criteria:

- **Fentanyl Patch:**
  - Member must meet one of the following criteria:
    - The member has an indication of cancer pain or palliative care pain
    - The member requires a long-acting narcotic and cannot tolerate an oral dosage form
  - Member must have a BMI ≥17
  - **Fentanyl Patch 12 mcg/hr**:
    - Member must meet one of the following (A or B):
    - A. The member must be receiving a total daily opioid dose less than or equal to 60 Morphine Equivalent Dose (MED), as evidenced by paid claims or pharmacy printouts
    - B. The member must be continuously tapering off opioids from a higher strength Fentanyl patch

Full Agonist Opioids Without Abuse Deterrent Formulations	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr	EXALGO (hydromorphone)
fentanyl 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
	KADIAN (morphine)
	morphine ER capsules
	MS CONTIN (morphine)
	oxycodone ER
	oxymorphone ER tablets
	ZOHYDRO ER (hydrocodone)

Opioid Analgesic – Short Acting

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

Product Specific Criteria:

- **Subsys, Fentanyl Citrate Buccal Tablet, Lazanda, Actiq, and Abstral:**
  - The member's age must be within label recommendations
  - The member must have a diagnosis of cancer pain
  - The member must currently be on around-the-clock opioid therapy for at least a week, as evidenced by paid claims or pharmacy printouts
    - The around the clock opioid therapy must be equivalent to 60 mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30mg oxycodone daily, 8 mg of oral hydromorphone daily, or equianalgesic dose of another opioid daily
- **ALL Other Non-Preferred Short-Acting Opioid Analgesics (Initial):**
  - The member must have required around-the-clock pain relief for the past 90 days, as evidenced by paid claims or pharmacy printouts
  - The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports
  - The member must have 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.)
  - The prescription must be written by or in consultation with an oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens)
- **Oxycodone IR**
  - The "ALL Other Non-Preferred Short-Acting Opioid Analgesics" above Initial Criteria must be met
  - The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Equivalent Dose (MED) 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 MED for specific products):
    - **Oxycodone 15 mg tablet:** long-acting opioid must provide ≥150 mg MED per day
    - **Oxycodone 20 mg tablet:** long-acting opioid must provide ≥200 mg MED per day
    - **Oxycodone 30 mg tablet:** long-acting opioid must provide ≥300 mg MED per day
- **Meperidine, butalbital-codeine products:**
  - The above Initial Criteria must be met
  - Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).
- **ALL Other Non-Preferred Short-Acting Opioid Analgesics (Renewal):**

- Documentation noting progress toward therapeutic goal must be included with request (including pain level and function).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine solution	ABSTRAL (fentanyl) SUBLINGUAL TABLET
acetaminophen-codeine tablets	ACTIQ (fentanyl) LOZENGE
benzhydrocodone-acetaminophen	butalbital-codeine
codeine tablets	CONZIP (tramadol) CAPSULE
hydrocodone-acetaminophen 7.5-325/15ml Solution	DEMEROL (meperidine)
hydrocodone-acetaminophen 5-325 MG	DILAUDID (hydromorphone)
hydrocodone-acetaminophen 7.5-325 MG	ENDOCET (oxycodone-acetaminophen)
hydrocodone-acetaminophen 10-325 MG	FENTORA (fentanyl) EFFERVESCENT TABLET
hydrocodone-ibuprofen 7.5mg-200mg	fentanyl citrate buccal tablet
hydromorphone liquid	fentanyl lozenge
hydromorphone tablet	hydrocodone-acetaminophen 5-163mg/7.5mL solution
meperidine	hydrocodone-acetaminophen 2.5-325 MG
morphine tablets	hydrocodone-acetaminophen 10MG-300MG
morphine solution	hydrocodone-acetaminophen 5 MG-300MG
NUCYNTA (tapentadol) TABLETS	hydrocodone-acetaminophen 7.5-300 MG
oxycodone 5mg, 10mg tablets	hydrocodone-ibuprofen 5mg-200mg and 10mg-200mg
oxycodone solution	LAZANDA (fentanyl) SPRAY
oxycodone-acetaminophen 5-325 MG	LORCET (hydrocodone-acetaminophen)
oxycodone-acetaminophen 10 -325 MG	LORTAB (hydrocodone-acetaminophen) SOLUTION
oxymorphone tablets	NALOCET (oxycodone-acetaminophen)
tramadol 50mg tablets	NORCO (hydrocodone-acetaminophen)
tramadol-acetaminophen tablets	OPANA (oxymorphone)
	OXAYDO (oxycodone)
	oxycodone 15mg, 20mg, 30mg
	oxycodone-acetaminophen 2.5-325 MG
	oxycodone-acetaminophen 7.5-325 MG
	PERCOCET (oxycodone/acetaminophen)
	PRIMLEV (oxycodone/acetaminophen)
	PROLATE (oxycodone/acetaminophen)
	QDOLO (tramadol) ORAL SOLUTION
	ROXICODONE (oxycodone)
	ROXYBOND (oxycodone)
	SUBSYS (fentanyl) SPRAY
	tramadol 100mg tablets
	ULTRACET (tramadol/acetaminophen)
	ULTRAM (tramadol)
	VICODIN (hydrocodone/acetaminophen)

Skeletal Muscle Relaxants

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - **Please call for an override** if all the following circumstances apply by calling provider relations at 1-800-755-2604:
    - Member has cerebral palsy or another chronic spastic disorder
    - Prescriber is a physiatrist
    - 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:
  - Antipsychotics: visual hallucinations being reported in 3% of members receiving tizanidine, psychosis has also been reported.
  - Other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa) as tizanidine is also an alpha 2 agonist

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 12 months*

- The member must have failed two 30-day trials of other skeletal muscle relaxants, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria

- **Metaxalone:** *Approval Duration = 12 months*
  - One of the required 30-day trials must be methocarbamol, as evidenced by paid claims or pharmacy printouts.
- **Carisoprodol:** *Approval Duration = 1 week*
  - The member must be undergoing dose tapering

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24HR
chlorzoxazone 500mg	chlorzoxazone 375mg and 750mg
cyclobenzaprine 5mg and 10mg	cyclobenzaprine 7.5mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	FEXMID (cyclobenzaprine)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	OZOBAX (baclofen) SOLUTION
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

Psychiatry

ADHD Agents

Therapeutic Duplication

- **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)
  - Cotempla XR-ODT (Methylphenidate)
  - Daytrana (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 suspension, Extended Release)
  - Mydayis (Mixed Salts of a Single-Entity Amphetamine Product)
  - 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 Adhansia XR with benzodiazepines or sedatives
    - Members reporting insomnia should use a shorter acting product that does not reach steady state.

- Methylphenidates: The following are not payable regimens
  - Concurrent use of dexmethylphenidate and methylphenidate

- **For all non-stimulants:**
  - One strength of one medication is allowed at a time except for Guanfacine 4mg IR and ER which may be combined Guanfacine IR and ER, respectively, to form dosages up to 7mg per day
  - Clonidine, guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)
    - Methyldopa and tizanidine are also alpha 2 agonists

First Fill

- Long-Acting ADHD medications (stimulants and guanfacine ER) must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Electronic Step Care and Concurrent Medication

***** Clonidine ER:** A total of 30 days of clonidine IR must be paid within 40 days prior to clonidine ER

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 10-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Qelbree:**
  - The member must have had a 30-day trial of a stimulant at the maximally tolerated dose, as evidenced by paid claims or pharmacy printouts

Non-Stimulants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	INTUNIV (guanfacine ER)
clonidine	KAPVAY (clonidine ER)***
clonidine ER***	STRATTERA (atomoxetine
guanfacine	
guanfacine ER	
QELBREE (viloxazine)PA	

Stimulants

Stimulants - Methylphenidates	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Solid Dosage Forms	
CONCERTA (methylphenidate) – *Brand Required*	dexmethylphenidate ER
dexmethylphenidate	FOCALIN (dexmethylphenidate)
FOCALIN XR (dexmethylphenidate) – *Brand Required*	METADATE ER (methylphenidate)
methylphenidate CD 30-70	methylphenidate ER tablet (generic Concerta)
methylphenidate tablet	methylphenidate LA capsules - 50-50 (generic Ritalin LA)
methylphenidate ER tablet 10mg, 20mg	RITALIN (methylphenidate)
RITALIN LA (methylphenidate LA capsules - 50-50)– *Brand Required*	
High Cost Options	
ADHANSIA XR (methylphenidate)	methylphenidate ER 72 mg
AZSTARYS (serdexmethylphenidate/dexmethylphenidate)	methylphenidate ER capsule
JORNAY PM (methylphenidate)	
Non-Solid Dosage Forms	
DAYTRANA (methylphenidate)	METHYLIN (methylphenidate) chew tablets
methylphenidate chew tablet	METHYLIN (methylphenidate) solution
methylphenidate solution	
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
High Cost Options	
APTENSIO XR (methylphenidate) – *Brand Required*	
COTEMPLA XR - ODT (methylphenidate)	

Stimulants - Amphetamines	
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Solid Dosage Forms	
ADDERALL XR (dextroamphetamine/amphetamine) – *Brand Required*	ADDERALL (dextroamphetamine/amphetamine)
amphetamine	DEXEDRINE ER (dextroamphetamine)
DESOXYN (methamphetamine) – *Brand Required*	dextroamphetamine/amphetamine ER
dextroamphetamine	EVEKEO (amphetamine)
dextroamphetamine ER	methamphetamine
dextroamphetamine/amphetamine	ZENZEDI (dextroamphetamine)
VYVANSE (lisdexamfetamine)	
High Cost Options	
MYDAYIS (dextroamphetamine/amphetamine)	
Non-Solid Dosage Forms	
DYANAVEL XR (amphetamine)	dextroamphetamine 5 mg/5 ml

Stimulants - Amphetamines	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
EVEKEO ODT (amphetamine)	
PROCENTRA (dextroamphetamine) – *Brand Required*	
High Cost Options	
ADZENYS XR - ODT (amphetamine)	ADZENYS ER (amphetamine) SOLUTION
amphetamine ER solution	
VYVANSE (lisdexamfetamine) CHEW TABLET	

Atypical Antipsychotics

Electronic Age Verification

- FDA or compendia supported age is required

Electronic Diagnosis Verification

- FDA or compendia supported indications is required

Therapeutic Duplication

Multiple Antipsychotic Override Request Form

- **For all antipsychotics:** One strength of one medication is payable with the following exceptions:
  - risperidone 0.25mg, 0.5mg and 1mg are allowed with other strengths of risperidone.
  - quetiapine 25mg and 50mg are allowed with other strengths of quetiapine IR.
  - quetiapine 50mg ER is allowed with other strengths of quetiapine ER.
  - olanzapine 2.5mg is allowed with 10mg, 15mg, and 20mg
  - olanzapine 5mg is allowed with 7.5mg and 20mg
  - olanzapine 7.5mg is allowed with 5mg
  - olanzapine 10mg, 15mg, and 20mg are allowed with 2.5mg
- Tizanidine is not allowed with antipsychotics due to visual hallucinations being reported in 3% of members receiving tizanidine, psychosis has also been reported. Please use an alternate muscle relaxant.
- Lybalvi: Lybalvi is not allowed with any other antipsychotic or opioid analgesics. Please call for an override to allow olanzapine with Lybalvi for dose titrations.

Additional information on olanzapine:

- Quantity limit is 1 tablet per day due to the 30-hour half-life of the medication.
- Pharmacokinetic studies show that olanzapine tablets and olanzapine ODT are bioequivalent.

Additional information on quetiapine:

- Quetiapine is not covered for sleep. For sleep indications, please use a sleeping medication indicated for insomnia.
- **For an override** for therapeutic duplication with quetiapine: Please call provider relations at 1-800-755-2604 if all of the following circumstances apply:
  - Nighttime akathisia (e.g. nighttime dosing with risperidone) or daytime sedation (e.g. Seroquel XR 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.

Oral

Electronic Step Care and Concurrent Medication

Vraylar requires initiation titration:

- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5mg dose: Initiation pack or 1 day of the 1.5mg tablet plus 6 days of 3 mg tablets is required

Underutilization

- Caplyta, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used compliantly and will reject on point of sale for late fill

First Fill

- Caplyta, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

Prior Authorization Criteria

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- ***olanzapine/fluoxetine**: Clinical justification must be provided explaining why the member is unable to use the preferred, individual products separately (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Solid Dosage Forms	
aripiprazole	ABILIFY (aripiprazole)
clozapine	asenapine
FANAPT (iloperidone)	CLOZARIL (clozapine)
INVEGA ER (paliperidone) – *Brand Required*	GEODON (ziprasidone)
LATUDA (lurasidone)	paliperidone ER
olanzapine	RISPERDAL (risperidone)
quetiapine	SEROQUEL (quetiapine)
quetiapine ER	SEROQUEL XR (quetiapine)
risperidone	ZYPREXA (olanzapine)
ziprasidone	
High Cost Options	
CAPLYTA (lumateperone)	olanzapine/fluoxetine***
LYBALVI (olanzapine/samidorphan)	
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	
Non-Solid Dosage Forms	
clozapine ODT	RISPERDAL (risperidone) ORAL SOLUTION
olanzapine ODT	RISPERDAL M-TAB (risperidone)
risperidone ODT	ZYPREXA ZYDIS (olanzapine)
risperidone oral solution	
SAPHRIS (asenapine) – *Brand Required*	
High Cost Options	
aripiprazole solution	ABILIFY DISCMELT (aripiprazole)
aripiprazole ODT	
SECUADO (asenapine)	

Long Acting Injectable

Electronic Step Care and Concurrent Medication

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.
    - Please call for exception if there is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	
PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

Sedatives/Hypnotics

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 due to CNS depression
        - Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines
- Ramelteon is a 1A2 Substrate and 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
- Benzodiazepines are not covered with Opioids: Override Criteria Available

Electronic Step Care and Concurrent Medications

- Zolpidem: Initiation with trial of 5 mg must be used for 7 days within 90 days prior to 10 mg tablets
    - Zolpidem is recommended to be used at lowest dose possible.
- Belsomra: The member must have had a 25- day trial of eszopiclone within the past 90 days

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria (Initial): *Approval Duration = 1 month*

- **temazepam, zolpidem SL, Dayvigo:**
    - The member's insomnia must be characterized by difficulty with sleep onset and maintenance
    - The member must have had the following 25-day trials with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
        - eszopiclone
        - zolpidem ER
        - Belsomra
- **Edluar (zolpidem):**
    - The member's insomnia must be characterized by difficulty with sleep onset
    - The member must have had the following 25-day trials with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
        - zolpidem IR
        - zaleplon
        - eszopiclone

- **triazolam, fluazepam, estazolam, seconal sodium**
    - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Product Specific Criteria (Renewal): *Approval Duration = 6 months (2 weeks for b*enzodiazepines)

- **ALL Agents:**
    - The prescriber has provided confirmation that other conditions causing sleep issues have been ruled out
- **benzodiazepines (temazepam, triazolam, flurazepam, estazolam):**
    - The member must be undergoing dose tapering

Insomnia

Non-DEA scheduled (non-addictive) medications:

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxepin – labeler 44183	doxepin – labeler 00228, 00378
hydroxyzine	ramelteon
mirtazapine	SILENOR (doxepin)
ROZEREM (ramelteon) – *Brand Required*	
trazodone	

DEA scheduled (addictive) medications:

PREFERRED AGENTS (NO PA REQUIRED)	ELECTRONIC STEP MEDICATIONS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eszopiclone	BELSOMRA (suvorexant)	AMBIEN (zolpidem)
zaleplon	zolpidem 10mg	AMBIEN CR (zolpidem)
zolpidem 5mg		DAYVIGO (lemborexant)
zolpidem ER		EDLUAR (zolpidem)
		estazolam
		flurazepam
		LUNESTA (eszopiclone)
		SECONAL SODIUM (secobarbital)
		temazepam
		triazolam
		zolpidem SL tab

Non-24 Hour Sleep-Wake Disorder

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
    - The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
    - The prescriber is a specialist, or the prescriber has consulted with a specialist in sleep disorders
    - The member must have had a 30-day trial of Rozerem (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.
- **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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ROZEREM (ramelteon) – *Brand Required*	HETLIOZ (tasimelteon)
	ramelteon

Pulmonology

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time (nebulizers and inhalers are not payable together)
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One long-acting beta agonist
  - One short acting beta agonist
    - 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.
    - **Please call for an override** if any of the following circumstances apply by calling provider relations at 1-800-755-2604:
      - Maximally treated members (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp) with end-stage COPD will be allowed an ongoing override
      - Acutely ill children will be allowed a one-time override
      - Members with cystic fibrosis will be allowed an ongoing override
- Anticholinergic medications are not covered with Acetylcholinesterase Inhibitors (Aricept, Exelon, Razadyne, Pyridostigmine). Click here for a full listing of medications included.
  - 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.

Concurrent Medication and Step Care

- Daliresp
  - A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 110 days prior to Daliresp's date of service.
    - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, Daliresp is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol/ Levalbuterol Rescue Inhalers

References:

2. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
3. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
4. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Healrth, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232

5. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Concurrent Medication and Step Care

- Ventolin HFA
  - A total of 30 days of steroid inhaler must be paid within 40 days prior to Ventolin HFA or ProAir Respiclick's date of service. The quantity limit for ProAir HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to Ventolin HFA and be on a steroid inhaler to control asthma.
    - According to the GINA guidelines:
      - A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
      - Dispensing ≥ 3 canisters per year is associated with higher risk of emergency department presentations
      - Dispensing ≥ 12 canisters per year is associated with higher risk of death
  - **Please call for an override:** if the following circumstance applies by calling provider relations at 1-800-755-2604:
    - If primary insurance will only pay for Ventolin HFA or ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).
- Xopenex HFA
  - A total of 30 days of albuterol HFA must be paid within 180 days prior to Xopenex HFA's date of service

Prior Authorization

General Prior Authorization Form
MedWatch Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROAIR (albuterol) HFA – *Brand Required*	albuterol HFA
PROAIR RESPICLICK (albuterol)	levalbuterol HFA
VENTOLIN (albuterol) HFA– *Brand Required*	PROAIR (albuterol) DIGIHALER
	PROVENTIL (albuterol) HFA
	XOPENEX (levalbuterol) HFA

Anticholinergics/Beta Agonists Combinations

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of 2 preferred, combination anticholinergic/long-acting beta agonist products, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Duaklir Pressair:**
  - The member must have had 30-day trials of Bevespi Aerosphere, 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)
ANORO ELLIPTA (umeclidinium/vilanterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)***
COMBIVENT RESPIMAT (albuterol/ipratropium)	DUONEB (albuterol/ipratropium)

STIOLTO RESPIMAT (tiotropium/olodaterol)	

Biologics

General Prior Authorization Form

Category Criteria (Initial): *Approval Duration = 3 months*

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist
- The member must have had at least 1 asthma exacerbation requiring use of oral corticosteroids in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation

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

Corticosteroids - Inhaled

Electronic Duration Verification:

- Budesonide Suspension 1mg/2mL is payable for 30 days every 75 days. Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5mg per day or lower, please use 0.5mg/2mL strength.
- For diluted nasal rinses, please use 0.5mg/2mL instead of 1mg/2mL for doses 1mg per day or higher.

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Alvesco, Armonair Digihaler**:
  - Member must have had a 30-day trial of Asmanex HFA, as evidenced by pharmacy claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ASMANEX (mometasone) TWISTHALER	ALVESCO (ciclesonide)***
budesonide Suspension	ARMONAIR DIGIHALER (fluticasone)***
FLOVENT DISKUS (fluticasone)	ARNUITY ELLIPTA (fluticasone)
FLOVENT HFA (fluticasone)	ASMANEX HFA (mometasone)
PULMICORT FLEXHALER (budesonide)	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

Long-Acting Anticholinergics

Electronic Diagnosis Verification

- Spiriva Respimat 1.25mg: Member must have a diagnosis of asthma
- All other long-acting anticholinergics must have a diagnosis of COPD

Concurrent Medication and Step Care

- Spiriva Respimat 1.25mg
  - A total of 30 days of a long-acting beta agonist (in combination or alone) must be paid within 40 days prior to Spiriva Respimat 1.25mg's date

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of at least 2 preferred long-acting anticholinergic agents, as evidenced by paid claims or pharmacy printouts.
    - Either single ingredient or combination products will count toward trials.

Product Specific Criteria:

- ***Lonhala Magnair**:
    - The member must have had a 30-day trial of Yupelri, 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	LONHALA MAGNAIR (glycopyrrolate)***
SPIRIVA HANDIHALER (tiotropium)	TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	YUPELRI (revefenacin)

Long-Acting Beta Agonists

General Prior Authorization Form

Group Criteria:

- **Generic non-preferred agents:** The member must have had a 10-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BROVANA (arformoterol) – *Brand Required*	arformoterol
PERFOROMIST (formoterol) – *Brand Required*	formoterol
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Steroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy printouts
- The member must have a diagnosis of an FDA-approved indication for use and meet the criteria for that diagnosis
    - **For COPD diagnosis:**
        A. The member must currently be taking a long acting antimuscarinic agent
    - **For asthma diagnosis:**
        - The member must have been reviewed for step down therapy for all renewal requests.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) – *Brand Required*	AIRDUO DIGIHALER (fluticasone/salmeterol)
ADVAIR HFA (fluticasone/salmeterol)	AIRDUO RESPICLICK (fluticasone/salmeterol)
DULERA (mometasone/formoterol)	BREO ELLIPTA (fluticasone/vilanterol)
SYMBICORT (budesonide/formoterol)) – *Brand Required*	budesonide/formoterol
	fluticasone/salmeterol
	WIXELA INHUB (fluticasone/salmeterol)

Steroid/Anticholinergics/Long-Acting Beta Agonists Combinations

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).

- **For COPD diagnosis:** the member must have had two 30-day trials of each of the following (either in combination or as single agents) as part of a maximized triple therapy, as evidenced by paid claims or pharmacy printouts:
    1. Long-Acting Anticholinergics
    2. Long-Acting Beta Agonist
    3. Inhaled Steroid
- **For asthma diagnosis:** the member must have had at least two 30-day trials of each of the following (either in combination or as single agents) in addition to Spiriva Respimat 1.25mg inhaler as part of a maximized triple therapy, as evidenced by paid claims or pharmacy printouts:
    1. Long-Acting Beta Agonist
    2. Inhaled Steroid

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Cystic Fibrosis

Cystic Fibrosis - Inhaled Antibiotics

General Prior Authorization Form

Product Specific Criteria:

- ***Tobi Podhaler:**
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
    - The member must have had a 28-day trial of a preferred nebulized product, as evidenced by paid claims or pharmacy printouts.
- ***Cayston:**
    - The member must be colonized with *Pseudomonas aeruginosa.*
    - The member must have had a 28-day trial of TOBI Podhaler, as evidenced by paid claims or pharmacy printouts.
- ***Arikayce:**
    - 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.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETHKIS (tobramycin)	ARIKAYCE (amikacin/nebulizer) ***
KITABIS PAK (tobramycin/nebulizer) - *Brand Required*	CAYSTON (aztreonam)***
TOBI PODHALER (tobramycin) PA***	TOBI (tobramycin) in 0.225% sodium chloride
tobramycin in 0.225% sodium chloride	tobramycin/nebulizer

Cystic Fibrosis – CFTR Modulators

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KALYDECO (ivacaftor)	
ORKAMBI (lumacaftor/ivacaftor)	

SYMDEKO (tezacaftor/ivacaftor)	
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)	

Cystic Fibrosis – Osmotic Agent

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Electronic Age Verification

- The member must be 18 years or older

Prior Authorization

- Documentation of the Bronchitol Tolerance Test must be submitted

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRONCHITOL (Mannitol) INHALER	

Idiopathic Pulmonary Fibrosis / Interstitial Lung Disease

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The prescriber must be, 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.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	
ESBRIET (pirfenidone)	
OFEV (nintedanib)	

Rheumatology

Biologics

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Concurrent Medication and Step Care

- Taltz***
  - A total of 90 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of a preferred agent from each class approved for patient's diagnosis, as evidenced by paid claims or pharmacy printouts.

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

Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)
PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti–interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
BEHCET'S SYNDROME	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
HUMIRA (adalimumab)	
Phosphodiesterase 4 (PDE4) Inhibitor	
OTEZLA (apremilast)	
GIANT CELL ARTERITIS (TEMPORAL ARTERITIS)	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	
JUVENILE IDIOPAHIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	
HUMIRA (adalimumab)	
NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
HUMIRA (adalimumab)	CIMZIA (certolizumab)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti–interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	
XELJANZ (tofacitinib) ORAL SOLUTION	
XELJANZ XR (tofacitinib)	
PSORIATIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)

Phosphodiesterase 4 (PDE4) Inhibitor	
OTEZLA (apremilast)	
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	XELJANZ XR (tofacitinib)
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
Anti – Interleukin (IL) 23 Antibodies	
	STELARA (ustekinumab)
	TREMFYA (guselkumab)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti – Interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
RHEUMATOID ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	OLUMIANT (baricitinib)
	RINVOQ (upadacitinib)
	XELJANZ XR (tofacitinib)
Anti-Interleukin-1 (IL-1) Receptor Inhibitors	
KINERET (anakinra)	
Anti – Interleukin 17 (IL) 17 Antibodies	
	COSENTYX (secukinumab)
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	KEVZARA (sarilumab)
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
SYSTEMIC ONSET JUVENILE CHRONIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	

Osteoporosis

Electronic Diagnosis Verification

- Risedronate 30mg requires FDA indication of Paget's Disease of the bone and is not indicated for osteoporosis

Oral Bisphosphonates

Prior Authorization Form - Osteoporosis

- 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:
    - Alendronate or Risedronate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)

alendronate oral solution	ATELVIA (risedronate DR)
ibandronate	FOSAMAX (alendronate)
risedronate IR	risedronate DR

Non-Oral Bisphosphonates

Prior Authorization Form - Osteoporosis

Non-Preferred Agents Criteria (Initial): *Approval Duration = 2 years*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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:
  - alendronate or risedronate
  - 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray	calcitonin, salmon
MIACALCIN (calcitonin, salmon) – *Brand Required*	EVISTA (raloxifene)
raloxifene	FORTEO (teriparatide)
teriparatide	TYMLOS (abaloparatide)

Substance Use

Nicotine / Tobacco Dependence Treatment

Concurrent Medication and Step Care

- A total of 14 days of Nicotine patch, Chantix, or Zyban must be paid within 40 days prior to Nicotrol Nasal Spray, nicotine lozenge, nicotrol inhaler, or nicotine gum's date of service.
  - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products.
- A total of 14 days of Nicotine patch, gum, lozenge, inhaler, or spray must be paid within 40 days prior to Zyban's date of service.
  - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products. Nicotine products can help bridge treatment until Zyban becomes effective.

Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months
  - Chantix:
    Please call for an override if the following conditions apply by calling provider relations at 1-800-755-2604:
    - Patent is abstinent from tobacco
    - Treatment duration is requested to be extended to 24 consecutive weeks

Therapeutic Duplication

- nicotine gum, lozenge, inhaler, and spray will not be paid concurrently
- Zyban will not be paid with other forms of bupropion

Underutilization

- Nicotine Patch, Chantix, and Bupropion must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	NICODERM CQ (nicotine) PATCH
CHANTIX (varenicline)	NICORETTE (nicotine polacrilex) GUM
nicotine lozenge	ZYBAN (bupropion SR)
nicotine patch	
nicotine polarcrilex gum	
NICOTROL (nicotine polacrilex) INHALER	
NICOTROL (nicotine polacrilex) SPRAY	

Opioid Use Disoder

Lucemyra

General Prior Authorization Form

Group Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- 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)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	LUCEMYRA (lofexidine)
guanfacine	

Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VIVITROL (Naltrexone Microspheres)	

Naloxone Rescue Medications

Please call for an override by calling provider relations at 1-800-755-2604:
The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:

- The provider must attest that it is known that the previous dose was taken by the member (and not diverted or given to another member)
- One of the following criteria must be met (A, B, or C)
    A. The previous dose has expired
    B. The dose was used by member for illicit drug use
    C. The member is currently taking opioids and meets one of the following criteria:
        - The opioid dose must have been decreased
        - The provider has provided medical justification why the opioid dose as not been Decreased

Non-Preferred Agents Criteria:

- The provider has provided medical justification explaining why the member cannot use Narcan Nasal Spray or injectable naloxone.

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

KLOXXADO (naloxone) NASAL SPRAY	
Naloxone injection	
NARCAN (naloxone) NASAL SPRAY	

Opioid Partial Agonist

Therapeutic Duplication

- One strength of one medication is allowed at a time
- Opioid Partial Agonists are not allowed with:
  - Methadone
  - Carisoprodol
  - Opioid Analgesics
    - **For an override,** please call provider relations at 1-800-755-2604 if all the following circumstances apply:
      - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)
      - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
      - Opioid duration is of a one-time occurrence or taper plan is provided

Underutilization

- Buprenorphine and buprenorphine/naloxone must be used compliantly and will reject on point of sale for late fill
- To request an override, submit a Opioid Use Disorder Underutilization Form. Both the 1st and 2nd pages must be filled out.

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

- *** **Buprenorphine tablets**: The member must be pregnant or breastfeeding, and estimated delivery date/duration of need for breastfeeding must be provided.

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of buprenorphine-naloxone SL tablets, 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).
- A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request
- DAW (Dispense As Written) Criteria must be met in addition to Opioid Partial Agonist Group PA Criteria.

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	BUNAVAIL FILM (buprenorphine/naloxone)
buprenorphine tablets[PA***]	buprenorphine/naloxone film
	SUBOXONE FILM (buprenorphine/naloxone)
	ZUBSOLV (buprenorphine/naloxone)

Non-Oral Agents

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

Obstetrics/Gynecology

Estrogens

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA approved or compendia supported indication
- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION – *Brand Preferred*	DEPO-ESTRADIOL (estradiol cypionate) INJECTION
PREMARIN (estrogens, conjugated) INJECTION	estradiol valerate 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
FEMHRT (norethindrone-ethyl estradiol) TABLET	BIJUVA (estradiol-progesterone) CAPSULE
norethindrone-ethinyl estradiol tablet	ESTRACE (estradiol) TABLET
PREMARIN (estrogens, conjugated) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
PREMPHASE (estrogen, conj.,m-progest) TABLET	JINTELI (norethindrone-ethinyl estradiol) TABLET
PREMPRO (estrogen, conj.,m-progest) TABLET	LOPREEZA (estradiol-norgestimate) TABLET
	MENEST (estrogens, esterified) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

Topical Cream/Gel/Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELESTRIN (estradiol) GEL	DIVIGEL (estradiol) GEL
EVAMIST (estradiol) SPRAY	

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	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone)	estradiol patch twice weekly
MENOSTAR (estradiol) PATCH	estradiol patch weekly
MINIVELLE (estradiol) PATCH TWICE WEEKLY - *Brand Required*	LYLLANA (estradiol) PATCH
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY - *Brand Required*	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ESTRING (estradiol)	ESTRACE (estradiol) CREAM
FEMRING (estradiol)	estradiol vaginal cream
PREMARIN (estrogens, conjugated) VAGINAL CREAM	estradiol vaginal tablet
VAGIFEM (estradiol) VAGINAL TABLET – *Brand Required*	YUVAFEM (estradiol) VAGINAL TABLET

Mifepristone

Prior Authorization Form - Mifeprex

Criteria for coverage: *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. The provider has provided a signed written statement indicating 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. The statement must indicate to whom the report was made.
        II. The provider has provided written statement signed by the recipient and the provider that the recipient's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the woman's statement.
    B. **Both of the following must be met (I and II)**
        I. The woman 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 woman in danger of death unless an abortion is performed
        II. The provider must provide a signed written statement indicating why, in the provider's professional judgement, the life of a woman would be endangered if the fetus were carried to term

Nausea/Vomiting

Pregnancy

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 3 months or until due date*

- Member must have diagnosis of nausea and vomiting of pregnancy
- Member's due date must be provided
- The prescriber must submit medical justification explaining why the member cannot use a preferred product (subject to clinical review)

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	

Uterine Fibroids

Electronic Diagnosis Verification

- The member must have an FDA approved indication

Electronic Age Verification

- The member must be 18 years of age or older

Prior Authorization Form

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 12 months*
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
    - The member must not be pregnant

- The provider must attest that the member does not have any contraindications to treatment with Oriahnn

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts (may be concurrent use):
  A. A 3-menstual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  B. A 3-menstual cycle trial of an oral estrogen-progestin or progestin contraceptives

- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must not have received ≥24 months of Oriahnn, as evidenced by paid claims or pharmacy printouts
  - The provider must attest that the member does not have any contraindications to treatment with Oriahnn
  - The member must have experienced and maintained clinical benefit since starting treatment with Oriahnn, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	
ORIAHNN (elagolix, estradiol, and norethindrone acetate)	

Orilissa

General Prior Authorization Form

Initial Criteria: *Approval Duration = 6 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  B. A 3-menstual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria: *Approval Duration = 18 months*

- Prescriber must submit documentation of improvement in pain score from baseline
- Request must be for maintenance dosing (150 mg strength).

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORILISSA (Elagolix)	

Progesterone

Prior Authorization Form - Makena

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The week of pregnancy and due date must be indicated on request (must be 20 weeks or greater).
- Clinical justification must be provided explaining why medication is medically necessary

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAKENA (hydroxyprogesterone caproate) – *Brand Required*	hydroxyprogesterone caproate

Vaginal Anti-Infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 30-day trials of 3 preferred vaginal anti-infective agents, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVC (sulfanilamide)	clindamycin cream
CLEOCIN (clindamycin) SUPPOSITORY	CLEOCIN (clindamycin) CREAM
CLINDESSE (clindamycin) CREAM	GYNAZOLE 1 (butoconazole) CREAM
clotrimazole	METROGEL-VAGINAL (metronidazole)
metronidazole gel	MICONAZOLE 3 (miconazole) SUPPOSITORY
NUVESSA (metronidazole) GEL	terconazole suppository
SOLOSEC (secnidazole)	VANDAZOLE (metronidazole) GEL
terconazole cream	
tinidazole	

Preferred Dosage Forms List:

General Prior Authorization Form

Criteria for coverage:

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- The member must have a diagnosis of an FDA-approved indication for use
- The member must not have any contraindication to the requested product
- The member must have failed* a therapeutic course** of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts.

**: A failure is defined as product was not effective at maximum tolerated dose or member has a documented intolerance or adverse reaction to inactive ingredients where the non-preferred product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the member*

***: Trials must have been at least 30 days in duration unless otherwise indicated*

Amoxicillin ER

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin IR	amoxicillin ER

Antihistamines

Therapeutic Duplication

- One strength of one medication is allowed at a time

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cetirizine chew tablet	desloratadine ODT
cetirizine Solution	levocetirizine solution
cetirizine tablet	
desloratadine tablet	
levocetirizine tablet	
loratadine solution	
loratadine tablet	

Bactroban

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Bactroban ointment	Bactroban cream

Belladonna Alkaloids/Phenobarbital

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
belladonna alkaloids/phenobarbital tablets	belladonna alkaloids/phenobarbital elixir

Bowel Prep Agents

Required trial duration: 1 complete dose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-G	CLENPIQ
GOLYTELY 227.1-21.5	COLYTE
MOVIPREP	GOLYTELY 236-22.74G
OSMOPREP	GAVILYTE-C
PEG-3350 AND ELECTROLYTES 236-22.74G	GAVILYTE-N
	NULYTELY
	PEG 3350-ELECTROLYTE 240-22.72G
	PEG 3350-ELECTROLYTE 420 G
	PEG 3350/SOD SUL/NACL/KCL/ASB/C
	PLENVU
	SUPREP
	SUTAB
	TRILYTE

Brisdelle (paroxetine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5mg capsules

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules
	ESGIC (butalbital-acetaminophen-caffeine) CAPSULES
	VANATOL LQ (butalbital-acetaminophen-caffeine) SOLUTION
	VANATOL S (butalbital-acetaminophen-caffeine) SOLUTION
	ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES

cyanacobalamin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyanocobalamin Injection	NASCOBAL (cyanocobalamin) NASAL SPRAY

Daxbia (cephalexin)

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

gabapentin

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

gabapentin	HORIZANT (gabapentin)
pramipexole	
ropinirole	

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
	deferasirox tablets
	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)
	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)
	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)
	QUTENZA (capsaicin/skin cleanser)
	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)

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Metformin ER	FORTAMET (metformin)
	GLUMETZA (metformin)
	RIOMET (metformin) ORAL SOLUTION
	RIOMET ER (metformin) ORAL SOLUTION

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate)
	RASUVO (methotrexate)
	REDITREX (methotrexate)
	TREXALL (methotrexate)

montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	

mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin Ointment	mupirocin calcium cream

nitroglycerin spray

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)

Onmel (itraconazole)

Required trial duration: 12 weeks with 6 months outgrow following treatment for onychomycosis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Itraconazole capsule	ONMEL (itraconazole) TABLET
terbinafine	

penicillamine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPEN (penicillamine) TITRATAB – *Brand Required*	CUPRIMINE (penicillamine) CAPSULE
	penicillamine capsule
	penicillamine tablet

potassium

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
potassium tablets	potassium solution
	potassium powder for solution

Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
	PROCYSBI GRANULES (cysteamine)

Siklos (hydroxyurea)

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

Steroids - Oral

Additional Criteria for coverage of Emflaza: See Emflaza Criteria on this document

Rayos required trial duration: 12 weeks with 2AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	DEXPAK (dexamethasone)
hydrocortisone	DXEVO (dexamethasone)
methylprednisone	EMFLAZA (deflazacort)

prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	HEMADY (dexamethasone)
prednisone solution	MILLIPRED (prednisolone)
prednisone tablets	ORTIKOS (budesonide)
	prednisone intensol
	prednisolone sodium phosphate ODT
	prednisolone sodium phosphate 10mg/5ml, 20mg/5ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

tacrolimus

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus	ASTAGRAF XL (tacrolimus)
	ENVARSUS ER (tacrolimus)

Tiglutik (riluzole)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole	RILUTEK (riluzole)
	TIGLUTIK (riluzole) ORAL SUSPENSION

Tirosint (levothyroxine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	levothyroxine capsules
TIROSINT (levothyroxine) 13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg 100 mcg 112 mcg, 125 mcg, 137 mcg, and 150 mcg capsule – *Brand Required*	SYNTHROID (levothyroxine) TABLET
	THYQUIDITY (levothyroxine) ORAL SOLUTION
	TIROSINT (levothyroxine) 175 mcg and 200 mcg capsule
	TIROSINT (levothyroxine) solution

Tussicaps

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocodone/chlorpheniramine ER suspension	TUSSICAPS (hydrocodone/chlorpheniramine)
promethazine/codeine	
ZODRYL AC (chlorpheniramine/codeine)	

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO 250 (ursodiol) TABLET
	URSODIOL AVPAK (ursodiol) CAPSULE
	URSO FORTE (ursodiol) TABLET

Medical Billing Drug Clinical Criteria

The following drugs/codes require prior authorization:

- Please submit the Medical Service Authorization Request long with any relevant chart notes.
- If a drug is not on this list, the drug does NOT need prior authorization unless being used for an indication outside of FDA indication.
- Unless drug has specific criteria outlined below, the following category criteria will be used:

Category Criteria:

Medical Service Authorization Request

Initial Criteria: *Approval Duration = 6 months (please specify infusion timeframe for one-time gene therapies)*

- Documentation of member meeting criteria as outlined by prescribing information (PI) including recommendations for diagnosis and age must be submitted.
- Additional Criteria may apply as outlined below (must be used as single agent therapy unless otherwise clinically indicated)

Renewal Criteria: *Approval Duration = 12 months*

- The provider 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).

Drug Name	Code
Aduhelm	J0172
Aldurazyme	J1931
Amondys 45	J1426
Blincynto	J9039
Breyanzi	Q2054
Brineura	J0567
Cerezyme	J1786
Crysvita	J0584
Danyelza	J9348
Elaprase	J1743
Elelyso	J3060
Evkeeza	J1305
Exondys 51	J1428
Fabrazyme	J0180
Gamifant	J9210
Givlaari	J0223
Ilaris	J0638
Kanuma	J2840
Krystexxa	J2507
Kymriah	Q2042
Lumizyme	J0221
Luxturna	J3398
Mepsevii	J3397
Naglazyme	J1458
Onpattro	J0222
Oxlumo	J0224
Radicava	J1301
Reblozyl	J0896

Soliris: ○ Paroxysmal Nocturnal Hemoglobinuria ○ Atypical Hemolytic Uremic Syndrome ○ Generalized Myasthenia Gravis ○ Neuromyelitis Optica Spectrum Disorder	J1300
Synagis	90378
Spinraza	J2326
Tecartus	Q2053
Tepezza	J3241
Ultomiris ○ Paroxysmal Nocturnal Hemoglobinuria ○ Atypical Hemolytic Uremic Syndrome	J1303
Uplizna	J1823
Viltepso	J1427
Vimizim	J1322
VPRIV	J3385
Vyepti	J3385
Vyondys 53	J1429
Yescarta	Q2041
Zolgensma	J3399

Aduhelm (aducanumab-avwa)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber must be, or in consult with, a specialist in neurology or gerontology
- The member has mild cognitive impairment (MCI) or mild Alzheimer's dementia due to Alzheimer's disease (Stage 3 or 4) as evidenced by all the following with the past 6 months:
  - Objective evidence of cognitive impairment at screening
  - Positron Emission Tomography (PET) scan or Cerebral Spinal Fluid (CSF) is positive for amyloid beta plaques
- Other conditions of non-Alzheimer's dementia etiology have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], Parkinson's Disease dementia)
- Member has received a baseline brain magnetic resonance imaging (MRI) within past year prior to initiating treatment verifying the member does not have the following:
  - acute or subacute hemorrhage
  - Macrohemorrhage
  - > 4 brain microhemorrhages
  - Any areas of superficial siderosis
- Prescriber has assessed and documented baseline disease severity utilizing one of the following scores (within the past 6 months):
  - Mini-Mental Status Exam (MMSE) score ≥ 21
  - Clinical Dementia Rating - Global Score (CDR-GS) ≤ 1.0
  - Montreal Cognitive Assessment (MoCA) ≥ 17

Category Criteria (Renewal): *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 (within the past 6 months):
  - CDR-GS of ≤ 1.0

- MMSE score ≥ 21
- MoCA ≥ 17

- Prior to the 5th, 7th, 12th infusion, documentation of recent (within the previous month) brain MRI showing one of the following:
  - ≤ 4 new incident microhemorrhages and 1 focal area of superficial siderosis
  - Radiographic stabilization since baseline (i.e., no increase in size or number of amyloid-related imaging abnormalities – hemosiderin deposition (ARIA-H))

Aldurazyme (laronidase)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber must be, or in consult with, a geneticist, pediatric metabolic specialist, hematologist, or specialist in mucopolysaccharidoses (MPS)
- The member must have a diagnosis of mucopolysaccharidosis type I (Hurler syndrome, Hurler-Scheie syndrome, Scheie syndrome with moderate to severe symptoms) with the following (as evidenced with submitted documentation):
  - 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
- The provider must submit documentation of the member's current motor function, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Category Criteria (Renewal): *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:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)

Atypical Hemolytic Uremic Syndrome (aHUS)

Soliris/Ultomiris

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber must be, or in consult with, a hematologist or nephrologist
- The member must have a diagnosis of atypical Hemolytic Uremic Syndrome (aHUS) with **one of** the following (as evidenced with submitted documentation):
  - Genetic testing confirming pathogenic mutations (e.g., CFH, CD46, CFI, C3, CFB, THBD, CFHR1, CFHR3, CFHR5)
  - Antibodies to complement factors inhibiting CFH or CFI activity
- Member has signs of TMA as evidenced by **all of** the following (as evidenced by submitted documentation):
  - Platelet count ≤ 150 x 109 /L
  - Hemolysis such as an elevation in serum lactate dehydrogenase (LDH)
  - Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis
- Member does not have TMA due to **one of** the following (as evidenced by submitted documentation):

- A disintegrin and metalloproteinase with thrombospondin type 1 motif, member 13 (ADAMTS13) deficiency (<10% activity for thrombotic thrombocytopenic purpura (TTP))
- Shiga toxin Escherichia coli related hemolytic uremic syndrome (STEC-HUS)
- Genetic defect in cobalamin C metabolism

Category Criteria (Renewal): *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

Brineura

Medical Service Authorization Request

Initial Criteria: *Approval Duration = 6 months*

- Member must be between 3 and 8 years of age.
- The member must have diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed 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)
- Brineura must be prescribed by or in consultation with a metabolic specialist, geneticist, or pediatric neurologist.
- 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
- 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*

Crysvita (burosumab)

Medical Service Authorization Request

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

- The member must have diagnosis of X-linked hypophosphatemia (XLH) or tumor-induced osteomalacia confirmed 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 prescriber must be, or in consult with a 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*

- The prescriber has provided documentation that the individual 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)

Duchenne Muscular Dystrophy (DMD)

Exondys-51/Vyondys-53/Amondys-45/ Viltepso

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 8 weeks*

- The member must be a male between ages of 4 and 19 years old
- The prescriber must be, or in consult with a neurologist specializing in treatment of DMD (submit documentation of formal consultation with specialist)
- The member must have an FDA-approved diagnosis confirmed by genetic test as recommended by manufacturer
- The prescriber must submit medical records confirming the member has:
    - 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
    - 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 be currently taking corticosteroids, as evidenced by paid claims or pharmacy printouts, and will continue taking with requested agent
- Weight and calculated dose must be provided consistent with approved FDA dose of 30 mg/kg infused once weekly 80 mg/day for Viltepso)
- 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)

Category Criteria (Renewal): *Approval Duration: 6 months*

- The prescriber must be, or in consult with, a neurologist specializing in treatment of DMD (submit documentation of formal consultation with specialist)
- The prescriber must submit medical records confirming the member has maintained:
    - 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen)	VYONDYS 53 (golodirsen)

EXONDYS 51 (eteplirsen)	
VILTEPSO (viltolarsen)	

Elaprase (idursulfase)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member has Hunter Syndrome (MPS II) confirmed by one of 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 member age must be 5 years of age or older
- The prescriber must be, 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)

Category Criteria (Renewal): *Approval Duration: 12 months*

- The member does not have severe cognitive or neurologic impairment (e.g. inability to swallow)
- 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%

Eosinophilic Asthma

Eosinophilic Asthma: See Clinical Criteria for Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQAIR (reslizumab)	
XOLAIR (omalizumab) VIALS	

Evkeeza (evinacumab-dgnb)

Hyperlipidemia: See Clinical Criteria for Pharmacy Billing

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member meets age and dosing requirements per prescribing information
- The prescriber is, or is in consult with a cardiologist, endocrinologist, or lipid specialist
- The member has homozygous familial hypercholesterolemia confirmed by documentation of one of the following:
  - 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 > 500mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of heterozygous familial hypercholesterolemia 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

Category Criteria (Renewal): *Approval Duration: 12 months*
- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction

Fabrazyme (agalsidase beta)

Galafold: See Clinical Criteria for Pharmacy Billing

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*
- The member is 8 years of age or older
- The prescriber is, 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 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
    - 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

Category Criteria (Renewal): *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

Gamifant

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date*
- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.

- The prescriber must be, or in consultation with a hematologist, oncologist, immunologist, or transplant specialist
- The member must have diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)
- 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
- The member must have one of 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.

Gaucher's Disease

Cerezyme/VPRIV/Elelyso

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber must be, or in consultation 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
- 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 (Initial):

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Category Criteria (Renewal): *Approval Duration: 12 months*

- The prescriber has provided documentation that the individual has demonstrated 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 1mg/dl
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone crisis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa)	CEREZYME (imiglucerase)
	VPRIV (velaglucerase alfa)

Givlaari (givosiran)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is, or is 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
- Member has addressed identifiable lifestyle triggers (e.g. certain drugs, smoking, stress)
- 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)
- Member has not had a liver transplant

Category Criteria (Renewal): *Approval Duration: 12 months*

- Member has not had a liver transplant
- 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

Ilaris (canakinumab)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a specialist, or the prescriber has consulted with a specialist in the area of the member's diagnosis.
- One of the following criteria is met:
  - The member has failed a 3-month trial of an interleukin-1 inhibitor (e.g. Kineret), interleukin-6 inhibitor (e.g. Actemra), or tumor necrosis factor (TNF)-blocker (e.g. Enbrel, Humira, Cimzia, and Simponi), as evidenced by paid claims or pharmacy print outs.
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Diagnosis Specific Criteria is met as outlined below.

Category Criteria (Renewal): *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.

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

- 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)

- 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.

Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

- The member has one of the following in addition to clinical feature of the disease:
    - Immunoglobulin D (IgD) is elevated (>14 mg/dL)
    - Immunoglobulin A (IgA) level is elevated (>260 mg/dL)
    - Mutations in the MVK gene or decreased MVK activity
    - Recurrent attacks with elevated serum inflammatory markers (e.g. C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))

Still's Disease

Includes: Adult-Onset Still's Disease (AOSD) and Systemic Juvenile Idiopathic Arthritis (SJIA)

- The member has at least two of the following symptoms (as evidenced by documentation):
    - Fever lasting for at least 2 weeks
    - Evanescent erythematous rash
    - Lymphadenopathy
    - Splenomegaly
    - Arthritis or arthragia

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

- 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

Kanuma (sebelipase alfa)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.

- The prescriber is a, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist
- Documentation must be attached to confirm one of the following:
    - Genetic testing confirming 2 mutations in the LIPA gene
    - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots

Category Criteria (Renewal): *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

Krystexxa (pegloticase)

Gout – See Clinical Criteria for Pharmacy Billing
Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, a rheumatologist
- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy print outs:
    - allopurinol at 300mg/day (or maximally tolerated dose) in combination with probenecid
    - febuxostat in combination with probenecid
- Failure of previous treatment must be documented by each of the following:
    - Serum uric acid level ≥ 6 mg/dL within the past month
    - Two or more gout flares per year or nonrevolving tophaceous deposits
- The member must have one or more of the following symptoms (as evidenced by documentation):
    - Greater than or equal to three gout flares in the previous 18 months
    - Greater than or equal to one gout tophus
    - Gouty arthritis

Category Criteria (Renewal): *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 both of the following:
    - Serum uric acid levels <6mg/dl within the past month
    - Decrease in gout flares or nonrevolving tophaceous deposits

Lumizyme (alglucosidase alfa)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, an endocrinologist, metabolic specialist or geneticist
- The member must have a diagnosis of Pompe disease confirmed by the following (as evidenced with submitted documentation):
    - 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 provider must submit documentation of the member's current motor function, as evidenced by scores from the following assessments:

    - Infantile-onset disease:
        - muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6MWT)
    - Late-onset (non-infantile) disease:
        - 6-minute walk test (6MWT)
        - Forced Vital Capacity (FVC) via Pulmonary Function Test
- The member must not have permanent invasive ventilation

Category Criteria (Renewal): *Approval Duration: 12 months*

- The member must not have permanent invasive ventilation
- 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:
    - Infantile-onset disease:
        - muscle weakness, motor function, respiratory function, cardiac involvement, percent predicted forced vital capacity (FVC), and/or 6-minute walk test (6MWT)
    - Late-onset (non-infantile) disease:
        - 6-minute walk test (6MWT)
        - Forced Vital Capacity (FVC) via Pulmonary Function Test

Luxturna (alglucosidase alfa)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 1 month (once per lifetime per eye)*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, 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.
- Patient has not previously received RPE65 gene therapy in intended eye.

Mepsevii (vestronidase alfa-vjbk)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, a metabolic or genetic specialist
- The member must have a diagnosis mucopolysaccharidosis VII (MPS VII, also known as Sly Syndrome) confirmed by both of the following (as evidenced with submitted documentation):
    - Deficiency of beta-glucuronidase enzyme
    - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The provider must submit documentation one or more of the following:
    - 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

Category Criteria (Renewal): *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

Naglazyme (galsulfase)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, a metabolic or genetic specialist
- The member must have a diagnosis mucopolysaccharidosis VI (MPS VI, also known as Maroteaux-Lamy syndrome) confirmed by both of the following (as evidenced with submitted documentation):
  - 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 provider must submit documentation both of the following:
  - 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 claim test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Category Criteria (Renewal): *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 claim test
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Onpattro (patisiran)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis

- The member must have a diagnosis of polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR) confirmed by both of the following (as evidenced with submitted documentation):
    - Any transthyretin (TTR) mutation confirmed by genetic testing
    - Clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability)
- The provider must submit documentation of one of the following:
    - Neuropathy Impairment Score (NIS) of five (5) or greater
    - Polyneuropathy disability (PND) score of ≤ IIIb
    - Familial amyloid polyneuropathy (FAP) of stage 1 or 2

Category Criteria (Renewal): *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 maintenance or improvement in the one of the following scores and symptoms:
    - NIS score
    - PND score
    - FAP stage

Oxlumo (lumasiran)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is, or in consult with, a nephrologist, urologist, geneticist or other healthcare provider experience in treating primary hyperoxaluria type 1 (PH1)
- The member must have a diagnosis of polyneuropathy of primary hyperoxaluria type 1 (PH1) confirmed by one of the following (as evidenced with submitted documentation):
    - 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
- Individual does not have secondary causes of hyperoxaluria (e.g., diet with excessive intake of oxalate, gastric bypass surgery, IBD, other intestinal disorders, etc.)
- Member has had at least a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day) that failed to achieve at least a 30% reduction in urinary oxalate excretion
- Patient has not received a liver transplant
- The provider must submit documentation of one of the following:
    - Elevated urinary oxalate excretion (ie, > 1 mmol/1.73 m2 per day [90 mg/1.73 m2 per day])
    - Elevated urinary oxalate:creatinine ratio as defined by age defined laboratory reference range
    - Elevated urinary excretion of glycolate (ie, > 0.5 mmol/1.73 m2 per day [45 mg/1.73 m2 per day])

Category Criteria (Renewal): *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:
    - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
    - Decreased or normalized urinary oxalate excretion
    - Decreased or normalized urinary oxalate:creatinine ratio relative to normative values for age
    - Decreased or normalized plasma oxalate and glyoxylate concentrations

Myasthenia Gravis

Soliris

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is, or in consult with, a neurologist
- The member must have a diagnosis of generalized Myasthenia Gravis
- The provider must submit documentation of **all of** the following:
    - The member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
    - The member has a Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score ≥ 6
    - The member has a positive serological test for anti-AChR antibodies (lab test must be submitted)
- The member has had a 90-day trial to pyridostigmine
- The member has had both of the following:
    - A 12-month trial (total duration) of at least two (2) immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide)
    - 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)

Category Criteria (Renewal): *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:
    - Decreased rate of Myasthenia Gravis exacerbations
    - A 3-point improvement in the member's total MG-ADL score
    - A 5-point improvement in quantitative MG total score

Neuromyelitis Optica Spectrum Disorder

Enspryng: Please see Clinical Criteria for Pharmacy Billing

Soliris/Uplizna

General Prior Authorization Form
Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is, or in consult with, a neurologist
- The member must have a diagnosis of Neuromyelitis Optica Spectrum Disorder (NMOSD)
- Member has positive serologic test for anti-AQP4 antibodies.
- Patient has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
- Patient has an Expanded Disability Status Score (EDSS) of ≤ 6.5
- Patient 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

Product Specific Criteria:

- Soliris: The member must have had a 3-month trial with Enspryng and/or Uplizna

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)

Paroxysmal Nocturnal Hemoglobinuria

Empaveli: Please see Clinical Criteria for Pharmacy Billing

Soliris/Ultomiris

Medical Service Authorization Request

Initial Criteria: *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- Must be prescribed by or in consultation with a hematologist, oncologist, or immunology specialist
- Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry with LDL level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages) demonstrating that individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (as evidenced by submitted documentation)
- Must have documented have one of the following at least 2 weeks before starting treatment:
  b. A full course of meningococcal, pneumococcal, and Hib vaccines
  c. A test for antibodies against encapsulated bacteria
  d. 2 weeks of antibacterial drug prophylaxis against S. *pneumoniae*, N. *meningitis*, and H. *influenzae* type B if vaccines are administered less than 2 weeks prior to starting therapy
- One of the following criteria must be met:
  - Member is transfusion-dependent
  - Member has hemoglobin ≤ 7 g/dL or Hb ≤ 9 g/dL and member has symptoms of thromboembolic complications (e.g. abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)

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
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
  - Normalization in LDH levels ≤ 280 U/L

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SOLIRIS (eculizumab)	
ULTOMIRIS (ravulizumab)	

Precocious Puberty

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FENSOLVI (leuprolide)	
LUPRON DEPOT (leuprolide)	
SUPPRELIN LA (histrelin)	
SYNAREL (nafarelin)	
TRIPTODUR (triptorelin)	

Radicava (edaravone)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, or in consult with, a neurologist or other healthcare provider experience in treating amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease.
- The member must have a diagnosis of amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease
- Member must be able to perform activities of daily living (ADLs) such as eating and moving around independently as documented by one of the following provided from the past 6 months:
    - ALS Functional Rating Scale-Revised (ALSFRS-R) score of greater than or equal to 2 in all items of the ALSFRS-R criteria at the initiation of treatment
    - Japanese ALS Severity Scale with a grade of 1 or 2
- The provider must submit documentation of both of the following:
    - "Definite" or "probable" amyotrophic lateral sclerosis (ALS), by the revised EL Escorial and Airlie House diagnostic criteria
    - Forced Vital Capacity (FVC) via Pulmonary Function Test ≥ 80%
- The member must not have permanent invasive ventilation
- Disease duration from onset of symptoms of less than 2 years

Category Criteria (Renewal): *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 one of the following scores provided from the past 12 months:
    - ALS Functional Rating Scale-Revised (ALSFRS-R) score of greater than or equal to 2 in all items of the ALSFRS-R criteria at the initiation of treatment
    - Japanese ALS Severity Scale with a grade of 1 or 2

Reblozyl (luspatercept)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is a, 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
- The provider must submit documentation of a pretreatment hemoglobin of less than 11g/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:
    - Diagnosis of hemoglobin S/β-thalassemia or alpha-thalassemia
    - Deep vein thrombosis or stroke within the past 24 weeks
    - Platelet count greater than 1000 x 109 per liter

Diagnosis Specific Criteria (Initial):

- For diagnosis for myelodysplastic syndrome/myeloproliferative neoplasm, the provider must submit documentation of the following:
    - The member requires 2 or more RBC units over an 8-week period
    - **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 diagnosis for anemia due to beta thalassemia, the provider must submit documentation of 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

Category Criteria (Renewal): *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
    - Dose will be increased to 1.25mg/kg daily
- Member continues to have pretreatment hemoglobin of less than 11g/dL

Spinal Muscular Atrophy (SMA)

Evrysdi: Please see Clinical Criteria for Pharmacy Billing

Spinraza

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 12 months*

- The member must have a diagnosis of spinal muscular atrophy (SMA) with the following (as evidenced with submitted documentation):
    - 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 (A and/or B):
        A. Member has number of SMN2 gene copies ≥ 1 but ≤ 3 as confirmed by genetic testing
        B. Member is symptomatic (e.g. loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
    - The medication must be prescribed by or in consultation with a neuromuscular neurologist or neuromuscular physiatrist
    - The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
    - 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 provider must submit documentation of the member's current motor function, as evidenced by scores from at least two of the following assessments
    A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
    B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
    C. Hammersmith Functional Motor Scale Expanded (HFMSE)
    D. Motor Function Measure – 32 items (MFM-32)
    E. Revised Upper Limb Module (RULM)
    F. 6-minute walk test (6MWT)
    G. Forced Vital Capacity (FVC) via Pulmonary Function Test
- The member must not have permanent invasive ventilation
- The member must not have severe contractures or severe scoliosis

Category Criteria (Renewal):: *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 Neurology clinic once per year and clinic name, contact information, and date of last visit must be provided
- The member must not have permanent invasive ventilation
- The member must not have severe contractures or severe scoliosis
- The provider must submit documentation 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 with Spinraza, 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

Zolgensma

Medical Service Authorization Request

Category Criteria: *Approval Duration = 1 month (Approval is limited to a single intravenous infusion per lifetime)*

- 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*
- Medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1×10^{14} vector genomes per kilogram)
- Baseline Documentation has been submitted 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.

Synagis

Prior Authorization Form - Synagis

Category Criteria: *Approval Duration = 5 months (allows for 5 monthly doses between October 19th through April 21st)*

- Member must have one of the following diagnoses (A, B, or C) and the additional criteria outlined for diagnosis:
    - **Prematurity:**
        - < 29 weeks, 0 days gestational age
        - ≤12 months of age at start of RSV season
    - **Chronic Lung Disease of Prematurity (CLD)**
        - ≤12 months of age at start of RSV season
            - < 32 weeks, 0 days gestational age

        - Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - 13-24 months of age at start of RSV season
        - < 32 weeks, 0 days gestational age
        - 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

Tepezza (teprotumumab-trbw)

Medical Service Authorization Request

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

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The medication must be prescribed by or in consultation with an endocrinologist, ophthalmologist, or specialist in the treatment of Graves' disease associated with Thyroid Eye Disease (TED)
- The member must have a diagnosis of moderate to severe Graves' disease associated with Thyroid Eye Disease
- The onset of Thyroid Eye Disease symptoms is within 9 months of request for treatment
- 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.

Vimizim (elosulfase alfa)

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration = 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber must be, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member must have a diagnosis of mucopolysaccharidosis type IVA (Morquio A syndrome) with the following (as evidenced with submitted documentation):
    - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
    - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- 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 claim test (3-MSCT)

Category Criteria (Renewal): *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 claim test (3-MSCT)
    - Reduced Urine Keratan Sulfate (KS) levels

Vyepti (eptinezumab-jjmr)

Migraine Prophylaxis: See Clinical Criteria for Pharmacy Billing

Medical Service Authorization Request

Category Criteria (Initial): *Approval Duration: 6 months*

- The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
- The prescriber is, or is in consult with a neurologist, or specialist in migraine treatment and prevention
- The member has a diagnosis of **one of** the following:
    - Episodic migraine defined as 4 to 14 headache days per month
    - Chronic migraine defined as 15 or more headache days per month of which 8 or more are migraine days
- The member must have had 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, divalproex sodium, metoprolol, nadolol, propranolol, timolol, topiramate, venlafaxine
- Prescriber must submit documentation, including clinical notes regarding:
    - Failure of prior treatments to reduce migraine frequency after 2-month trial
    - Baseline average monthly migraine days
- The member has had a 90-day trial with each self-administered CGRP (Ajovy, Emgality, and Aimovig)

Category Criteria (Renewal): *Approval Duration: 12 months*

- The member must have experienced at least a 50% reduction in migraine days from baseline, since starting treatment with eptinezumab-jjmr (Vyepti).

Preferred Diabetic Supply List (PDSL)

Electronic Step Care and Concurrent Medications

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.

- A total of a 25-day supply of Insulin and/or Sulfonylurea therapy must be paid within 150 days prior to diabetic supplies' date of service.
- Gestational Diabetes is a covered indication for diabetic testing supplies. Members with gestational diabetes must have prenatal vitamins or folic acid preparations in their prescription claim history for testing supplies to pay.
- Newly diagnosed, acutely ill, or have a significant change in health status for medically necessary purposes: overrides for a period of 6 months will be considered

Preferred Test Strips

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

Preferred Meters

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
LifeScan Inc.	53885-0194-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0208-01	OneTouch Ultra Mini Blood Glucose Meter
LifeScan Inc.	53885-0267-01	OneTouch Verio IQ Blood Glucose Meter
LifeScan Inc.	53885-0448-01	OneTouch Ultra 2 Blood Glucose Meter
LifeScan Inc.	53885-0657-01	OneTouch Verio Blood Glucose Meter
LifeScan Inc.	53885-0927-01	OneTouch Verio Reflect System
Ascensia Diabetes Care	00193-7377-01	Contour Next Blood Glucose Meter
Ascensia Diabetes Care	00193-7252-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7189-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9545-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9628-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7553-01	Contour Next EZ Blood Glucose Meter

Ascensia Diabetes Care	00193-7818-01	Contour Next One Blood Glucose Meter

Continuous Glucose Monitors

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

Quantity limits:

- NDC 08627005303- Dexcom G6 Sensors 3 ten-day sensors/box= up to qty 9/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter- 1= 90-day supply (4 Transmitters/year)
- NDC 08627009011- Dexcom G6 Receiver- 1= 250-day supply (warranty is 1 year)

Prior Authorization Criteria

Continuous Glucose Monitor (CGM) Prior Authorization Form

Initial Criteria: *Initial Approval 12 months*

- Patient must meet one of the following criteria:
  1. Patient uses basal and prandial insulin doses, or Humulin R U-500 **OR**
  2. Patient uses an insulin pump **OR**
  3. Patient is pregnant with diagnosis of gestational diabetes **OR**
  4. Patient has recurrent hypoglycemia due to one of the following diagnoses and CGM is recommended by a medical geneticist or an endocrinology specialist as evidenced by chart notes:
     - Inborn errors of metabolism/metabolic syndrome with risk of hypoglycemia (e.g. glycogen storage disease (GSD), hereditary fructose intolerance (HFI), fatty acid oxidation disorders, gluconeogenesis disorders, ketogenesis disorders)
     - Hyperinsulinemia syndromes (e.g. Insulinoma, Persistent Hyperinsulinemia Hypoglycemia of Infancy (PHHI), Non-insulinoma Pancreatogenesis Hypoglycemia Syndrome (NIPHS), Nesideoblastosis)
- Prescriber must attest to all the following:
  - Patient will maintain regular provider visits to review glycemic control every 3-6 months.
    - CGM data will be reviewed at provider office visits.
    - CGM data will be used in the clinical decision-making process and documented in chart notes
  - Prescriber must provide most recent A1C for patients with diabetes.

Renewal Criteria: *Approval 12 months*

- Prescriber must submit the current or most recent Time in Range percentage.
- CGM data must have been reviewed with a documented decision-making process, as evidenced by a submitted progress note within the past 6 months.
- Prescriber must provide most recent A1C for patients with diabetes.

Test strips policy 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 Dexcom G6 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?
- The following criteria will apply if Dexcom G6 has previously been paid, but will no longer be used and regular test strip quantities are requested:

- 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

CGM Supplies Coverage FAQ

Does ND Medicaid cover Dexcom G6 daily calibration?

- No, the unique Dexcom G6 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?

Will test strips be covered in addition to Dexcom G6?

- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom G6 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 G6, is there a grandfathering period?

- No, the member should be converted to Dexcom G6 billed on the pharmacy side to obtain ND Medicaid coverage.

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.

Can members currently receiving CGM through Medicaid Expansion continue to receive CGM?

- Medicaid Expansion members: currently, Sanford Health Plan pays for CGM as medical claims. Effective July 1, 2021, these claims will have to be billed as pharmacy claims for Dexcom G6. Members will need to convert to Dexcom G6 if another CGM is currently being utilized.
- ND Medicaid has pre-emptively entered initial prior authorizations for Medicaid Expansion members utilizing Dexcom G6 for 1 year. ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the grandfathering period.

Will members currently receiving CGM through Special Health Services (SHS) continue to receive CGM?

- Effective July 1, 2021, members receiving Dexcom will need to bill ND Medicaid for Dexcom G6. 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 Dexcom G6 for 1 year. ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the grandfathering period.
- Members receiving CGM other than Dexcom G6 will need to continue to work with SHS for CGM coverage.

Billing FAQ

If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this still 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 G6 billed on the pharmacy side to obtain ND Medicaid coverage.

Will ND Medicaid cover Dexcom G6 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 G6, will ND Medicaid pay the copay?

- If primary insurance excludes coverage of a Dexcom G6, ND Medicaid may make an exception to cover a non-preferred CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom G6, the member will need to switch to Dexcom G6 for ND Medicaid to pay the copay.

Does ND Medicaid cover Dexcom G6 if member has primary insurance, but it does not cover CGM?

- ND Medicaid may cover Dexcom G6 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 G6 if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Dexcom G6 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 G6 benefit.

Other Utilization Review Policy

Therapeutic Duplication

Therapeutic duplication descriptions for medications on the PDL are embedded within those categories. This is a listing of therapeutic duplication categories on medications that are not managed by the PDL for selected therapeutic duplication categories.

Antidepressant Medications

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - Bupropion
    - Mirtazapine
    - Selegiline
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Fetzima, Viibryd, or Brintellix are not allowed with other antidepressant medications
  - Exceptions: trazodone and mirtazapine
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Benzodiazepines

- 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.
- Benzodiazepines indicated only for insomnia are not allowed with other non-barbiturate insomnia medications or other benzodiazepines
- Long-Acting Benzodiazepines are not covered with sleeping medication due to CNS depression
  - Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines
- 3A4 Substrates (alprazolam, clonazepam, midazolam,) are not allowed with strong 3A4 inhibitors.

Long-Acting Contraception

- One strength of one medication is allowed at a time

Anticholinergics and Acetylcholinesterase Inhibitors

Anticholinergics	Acetylcholinesterase Inhibitors
Anoro Ellipta (Umeclidinium Bromide/Vilanterol)	Aricept (donepezil)
Atrovent HFA (Ipratropium Bromide)	Exelon (Rivastigmine)
Benztropine	Razadyne (Galantamine)

Bevespi Aerosphere (glycopyrrolate/formoterol)	Pyridostigmine
Breztri aerosphere (budesonide/glycopyrrolate/formoterol)	
Combivent Respimat (Ipratropium/Albuterol)	
Cuvposa (Glycopyrrolate)	
Detrol (tolterodine)	
Dicyclomine	
Enablex (Darifenacin)	
Glycopyrrolate	
Incruse Ellipta (Umeclidinium Bromide)	
Lonhala Magnair (glycopyrrolate)	
Oxybutynin	
Propantheline	
Spiriva (Tiotropium Bromide)	
Spiriva Respimat (Tiotropium Bromide)	
Stiolto Respimat (Tiotropium/Olodaterol)	
Toviaz (Fesoterodine)	
Trelegy Ellipta (Fluticasone/Umeclidinium/Vilanterol)	
Trihexyphenidyl	
Trospium	
Tudorza Pressair (Aclidinium Bromide)	
Vesicare (Solifenacin)	
Yupelri (Revefenacin)	

CYP450 3A4 Interactions

Strong 3A4 Inhibitors	3A4 Substrates
Atazanavir	Alprazolam
Clarithromycin	Clonazepam
Cobicistat	Corlanor
Darunavir	Fentanyl
Dasabuvir	Midazolam
Idelaisib	Methadone
Indinavir	Oxycodone
Itraconazole	Qulipta 30mg and 60mg
Ketoconazole	
Lopinavir	
Mifepristone	
Nefazodone	
Nelfinavir	
Ombitasvir	
Paritaprevir	
Posaconazole	
Ritonavir	
Saquinavir	
Telithromycin	
Voriconazole	

Electronic Step Care and Concurrent Medications

Electronic Step Care and Concurrent Medications for medications on the PDL are embedded within those categories. This is a listing of Electronic Step Care and Concurrent Medications on medications that are not managed by the PDL.

Antidepressants

- Trintellix: 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: 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

First Fill for medications on the PDL are embedded within those categories. This is a listing of First Fill on medications that are not managed by the PDL.

Antidepressants

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

Prior Authorization Review Dates

Date	Category
12/1/2021	Non-Stimulants for ADHD
9/1/2021	Heart Failure
9/1/2021	Nasal Polyps
9/1/2021	Chronic Idiopathic Urticaria
9/1/2021	Uterine Fibroids
9/1/2021	Sedative/Hypnotics - Hetlioz
6/2/2021	Sickle Cell Disease
6/2/2021	Fabry Disease
6/2/2021	Imcivree
6/2/2021	Bowel preparation agents
3/3/2021	Evrysdi
3/3/2021	Hereditary angioedema
3/3/2021	Irritable bowel syndrome
12/2/2020	Agents for the treatment of diabetic gastroparesis
12/2/2020	Oriahnn
12/2/2020	Dojolvi
9/2/2020	Palforzia
9/2/2020	Mytesi
9/2/2020	Antifibrinolytic agents
9/2/2020	ACL inhibitors (Nexletol, Nexlizet)
9/2/2020	Cystic fibrosis agents
6/3/2020	Conjupri
3/4/2020	Glucagon agents
3/4/2020	Ofev for treatment of scleroderma with interstitial lung disease
12/4/2019	antifungal agents for aspergillus and candidiasis infections
12/4/2019	eosinophilic asthma agents
9/4/2019	short-acting opioid analgesic agents
9/4/2019	agents for the treatment of thrombocytopenia
9/4/2019	agents for the treatment of interstitial cystitis
9/4/2019	agents for the treatment of narcolepsy
6/5/2019	Sivextro
6/5/2019	Nuzyra
6/5/2019	agents for treatment of osteoporosis
6/5/2019	agents for treatment of hyperkalemia
6/5/2019	agents for treatment of Parkinson’s disease
4/9/2019	Orilissa
4/9/2019	agents for treatment of vaginal anti-infectives
4/9/2019	agents for treatment of glaucoma
4/9/2019	agents for treatment of dry eye syndrome
12/5/2018	glyburide and Avandia
12/5/2018	Lucemyra

12/5/2018	Palynziq
12/5/2018	Roxybond
12/5/2018	Siklos
6/6/2018	Anzemet and Zuplenz
6/6/2018	biosimilar agents
6/6/2018	topical corticosteroid agents
6/6/2018	Dupixent
6/6/2018	Gocovri
6/6/2018	Tussicaps
3/7/2018	Skelaxin
3/7/2018	Eucrisa
9/6/2017	Proglycem
9/6/2017	Biltricide
3/1/2017	prednisolone ODT, Millepred, Veripred
3/1/2017	metformin OSM
3/1/2017	testosterone oral
12/7/2016	Namenda XR
12/7/2016	Dihydroergotamine
12/7/2016	Tetracycline
12/7/2016	Spiriva Respimat 2.5 mcg
12/7/2016	ophthalmic corticosteroids
12/7/2016	erythropoiesis-stimulating agents
9/7/2016	kits
9/7/2016	dipeptidyl peptidase-4 (DPP-4) inhibitors
9/7/2016	immunoglobulins
9/7/2016	bowel preparation agents
9/7/2016	topical agents used to treat plaque psoriasis
9/7/2016	platelet aggregation inhibitors
9/7/2016	antihyperuricemics
6/1/2016	Glumetza
6/1/2016	naloxone rescue medications
6/1/2016	naltrexone
6/1/2016	Edecrin
6/1/2016	interleukin-5 antagonist monoclonal antibodies
6/1/2016	acitretin
6/1/2016	lice medications
6/1/2016	NK1 receptor antagonists
6/1/2016	Tirosint
3/2/2016	insulins
3/2/2016	steroid inhalers
3/2/2016	digestive enzymes
3/2/2016	nasal steroids
3/2/2016	otic anti-infectives
3/2/2016	ulcer anti-infectives

12/2/2015	Marinol
12/2/2015	skin pigment products
12/2/2015	inhaled corticosteroid/LABA combination products
12/2/2015	Movantik
12/2/2015	medications used to treat irritable bowel syndrome/OIC
12/2/2015	medications used to treat ulcerative colitis
12/2/2015	SGLT2 products
12/2/2015	immediate release oxycodone
12/2/2015	inhaled anti-infectives for cystic fibrosis
12/2/2015	leukotriene modifiers
9/2/2015	cholesterol lowering drugs/PCSK9 inhibitors
9/2/2015	injectable anticoagulants
9/2/2015	Akynzeo
9/2/2015	Nuvessa
9/2/2015	Cholbam
6/3/2015	Otezla
6/3/2015	Xtoro
6/3/2015	Hemangeol
6/3/2015	Lemtrada
6/3/2015	agents used to treat idiopathic pulmonary fibrosis
6/3/2015	GLP-1 receptor agonists
6/3/2015	topical therapies for onychomycosis
12/3/2014	testosterone products
12/3/2014	phosphate binders
12/3/2014	Zontivity
12/3/2014	Evzio
9/3/2014	Northera
9/3/2014	Oral Allergen Extracts
6/2/2014	Cathflo
6/2/2014	Intranasal Cyanocobalamin Products
6/2/2014	Luzu
6/2/2014	Noxafil
6/2/2014	Bethkis
3/3/2014	Statins
3/3/2014	Vecamyl
12/3/2013	Brisdelle
12/3/2013	Nitroglycerin Lingual Spray/Sublingual Tablets
12/3/2013	Agents Used to Treat COPD
12/3/2013	Epinephrine Auto-Injection Devices
12/3/2013	Pulmozyme
9/9/2013	Rayos
9/9/2013	Diclegis
9/9/2013	Sitavig
9/9/2013	Onmel

9/9/2013	Giazo
6/3/2013	Fulyzaq
6/3/2013	Xeljanz
3/11/2013	Genitourinary Smooth Muscle Relaxants
3/11/2013	Agents Used to Treat Multiple Sclerosis
12/3/2012	Actinic Keratosis
12/3/2012	Moxeza
9/17/2012	Kalydeco
9/17/2012	Kuvan
9/17/2012	Elaprase
6/4/2012	Lorzone
6/4/2012	Provigil
6/4/2012	Kapvay
6/4/2012	Dexpak/Zemapak
6/4/2012	Xifaxan
6/4/2012	Vanos
3/5/2012	Pulmonary Arterial Hypertension Agents
3/5/2012	Topical Acne Agents
3/5/2012	Benign Prostatic Hyperplasia Agents Brendan
3/5/2012	Juvisync/Combination Products
3/5/2012	Gralise
12/5/2011	Dificid
12/5/2011	New Oral Anticoagulants
12/5/2011	agents used to treat Hereditary Angioedema
9/12/2011	Asacol HD
9/12/2011	Ophthalmic Antihistamines
9/12/2011	Horizant
9/12/2011	Daliresp
9/12/2011	narcotics with high dose APAP
6/6/2011	Nuedexta
6/6/2011	Nexiclon
6/6/2011	Topical ketoconazole products
3/7/2011	Statins
3/7/2011	Gilenya
3/7/2011	Xyrem
12/6/2010	agents used to treat Hepatitis C
12/6/2010	ODT preparations
12/6/2010	Oravig
12/6/2010	Zyclara
12/6/2010	Clorpres
12/6/2010	Livalo
12/7/2009	Hemophilia
12/7/2009	Sancuso
12/7/2009	Relistor

12/7/2009	Nuvigil
12/7/2009	Nucynta
9/14/2009	Uloric
9/14/2009	Moxatag
9/14/2009	Targeted Immune Modulators
6/1/2009	Aczone
12/1/2008	Triptans
12/1/2008	Vusion
9/8/2008	Chantix
9/8/2008	Carisoprodol
2/4/2008	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
5/1/2006	Growth Hormone
5/1/2006	Sedative/Hypnotics Agents
2/13/2006	Actoplus met
11/7/2005	Revatio
8/8/2005	Zanaflex capsule