



## CDPHP<sup>®</sup> Medicare Advantage 2025 Part D Prior Authorization Criteria

The following guidelines outline the Part D drugs that require prior authorization through the CDPHP pharmacy department. *Please be aware that these guidelines do not reflect those instances in which it is the member's responsibility to seek prior authorization.*

Coverage for a service is subject to the member's eligibility, specific contract benefits, and CDPHP policy. Requests for a service that does not meet criteria outlined in the CDPHP Medicare Advantage pharmacy policies or for an extension beyond what has been approved by CDPHP should be directed to the pharmacy department at (518) 641-3784.

### ABIRATERONE

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

### ACNE

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** Cosmetic Use

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Enrollee has tried or prescriber has considered using one of the accepted therapies noted in national guidelines, including, but not limited to topical benzoyl peroxide, topical antibiotics, systemic antibiotics but deemed one or all of them inappropriate for the enrollee.

### ACTIMMUNE

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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AIMOVIG <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>REQUIRED MEDICAL INFORMATION:</b> The requested drug will be covered when the following criteria are met: 1) The requested drug is being prescribed for the preventative treatment of migraine in an adult patient AND a) The patient has experienced an inadequate treatment response with an 8 week trial of any of the following: antiepileptic drugs, beta-adrenergic blockers, antidepressants OR b) the patient received at least 3 months of treatment with the requested drug and the patient has had a reduction in migraine days per month from baseline <b>COVERAGE DURATION:</b> Initial approval 3 months, continuation 12 months
ALDURAZYME <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
AKEEGA <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ALECENSA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ALPHA1-PROTEINASE INHIBITOR <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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ALUNBRIG <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ARANESP <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ARCALYST <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ARIKAYCE <b>PA INDICATION:</b> All FDA-Approved Indications <b>REQUIRED MEDICAL INFORMATION:</b> Criteria for initial approval require ALL of the following: 1. Diagnosis of refractory Mycobacterium avium complex (MAC) lung disease AND 2. Patient has received treatment with at least six consecutive months of combination antibacterial treatment AND 3. Requested agent will be used as part of a combination antibacterial regimen <b>AGE RESTRICTIONS:</b> 18 years and older <b>PRESCRIBER RESTRICTIONS:</b> Prescribed by or in consultation with a Pulmonologist or Infectious Disease specialist <b>COVERAGE DURATION:</b> 12 months <b>OTHER CRITERIA:</b> Criteria for renewal approval require that the patient has been previously approved for the requested agent AND has an appropriate FDA approved diagnosis AND has had clinical benefit with the requested agent

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<p>ARMODAFINIL</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another target agent (i.e., modafinil)</p> <p><b>AGE RESTRICTIONS:</b> 17 years of age or over</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>AUGTYRO</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>AUSTEDO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>AGE RESTRICTION:</b> 18 years and older</p> <p><b>PRESCRIBER RESTRICTION:</b> Prescribed by or in consultation with a psychiatrist or neurologist</p> <p><b>COVERAGE DURATION:</b> Initial approval 3 months. Renewal requests if policy criteria met 6 months</p>
<p>AYVAKIT</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>BALVERSA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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<p><b>BENLYSTA</b></p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p><b>BENZODIAZEPINES</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> A. If for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety, the patient has experienced an inadequate treatment response to one formulary drug indicated for anxiety including, but not limited to buspirone, duloxetine, escitalopram, venlafaxine or paroxetine AND B. If the patient is 65 years of age or older, the benefit of therapy with the prescribed medication outweighs the potential risk.</p> <p><b>COVERAGE DURATION:</b> Alcohol Withdrwl-1mo, Anxiety-6mo, Muscle Spasms-reflex 6mo,motor neuron disorder-Seizures-Plan Year</p>
<p><b>BERINERT</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p><b>BESREMI</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p><b>BEXAROTENE</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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BRUKINSA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
CABOMETYX <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
CALQUENCE <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
CAMZYOS <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
CAPRELSA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
CARGLUMIC ACID <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<p>CERDELGA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>CEREZYME</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>CLOBAZAM</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>COBENFY</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>COMETRIQ</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>COPIKTRA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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## COSENTYX

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis or plaque psoriasis NO prerequisites are required for diagnoses of ankylosing spondylitis, enthesitis related arthritis, hidradenitis suppurativa, or non-radiographic axial spondyloarthritis Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

## COTELLIC

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

## CYSTAGON

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<p>CYSTEAMINE OPHTHALMIC</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>DAURISMO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>DAYBUE</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>DEFERASIROX</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>DHE NASAL</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>DOPTelet</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>PRESCRIBER RESTRICTIONS:</b> Prescribed by or in consultation with a hematologist, hepatologist, or surgeon</p> <p><b>COVERAGE DURATION:</b> 12 months</p>

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DRIZALMA

**PA INDICATION:** All FDA-Approved Indications

**COVERAGE DURATION:** 12 months

DROXIDOPA

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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## DUPIXENT

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** Atopic Dermatitis: The enrollee must have a diagnosis of moderate-to-severe chronic atopic dermatitis and have an inadequate response, intolerance, or contraindication with one medium to very high potency topical corticosteroid OR atopic dermatitis affecting only the face, eyelids, skin folds, and/or genitalia and have an inadequate response, intolerance, or contraindication with one topical calcineurin inhibitor (e.g., tacrolimus ointment). Asthma: The enrollee must have a diagnosis of moderate to severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma and Dupixent must be requested to be used as add-on maintenance treatment with standard of care asthma drugs (e.g., inhaled corticosteroids, leukotriene modifiers, long-acting beta agonists, long-acting muscarinic antagonists). For renewal requests Dupixent must continue to be used with standard of care asthma drugs. Chronic rhinosinusitis with nasal polyposis: The enrollee must have a diagnosis of chronic rhinosinusitis with nasal polyposis and have an inadequate response, intolerance, or contraindication with a systemic corticosteroid and have an inadequate response, intolerance, or contraindication with an intranasal corticosteroid OR have had prior surgery for nasal polyps. Eosinophilic esophagitis: The enrollee must have a diagnosis of eosinophilic esophagitis confirmed by an endoscopic biopsy demonstrating greater than or equal to 15 intraepithelial eosinophils per high-power field and not have a secondary cause of eosinophilic esophagitis, and have received at least 8 weeks of treatment with a prescription strength proton pump inhibitor. Prurigo nodularis: The enrollee must have a diagnosis of prurigo nodularis and have greater than or equal to 20 nodular lesions and AND have tried at least 1 medium to very high potency prescription topical corticosteroid. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype: The enrollee is currently being treated with AND will continue COPD control therapy (e.g. ICS, LABA, LAMA) in combination with the requested agent AND the enrollee will NOT be using the requested agent in combination with Xolair or with an injectable interleukin 5 (IL-5) inhibitor (e.g. Cinqair, Fasenra, Nucala) for the requested indication. For all diagnosis listed the requested dose must be within FDA labeled dosing.

**AGE RESTRICTIONS:** None

**PRESCRIBER RESTRICTIONS:** Atopic Dermatitis/prurigo nodularis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist. Esophagitis-prescribed by or in consultation with an allergist or gastroenterologist. COPD with eosinophilic phenotype-prescribed by or in consultation with a pulmonologist.

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Criteria for renewal approval require that the patient has been previously approved for the requested agent AND has the appropriate FDA approved diagnosis AND has had clinical benefit with the requested agent AND the requested dose is within FDA labeled dosing for the requested indication.

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## DUVYZAT

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** Enrollee is non-ambulatory or has any of the following: platelet count below the lower limit of normal (see individual lab normal value range); symptomatic cardiomyopathy or heart failure (NYHA Class III or IV) or LVEF less than 50%; QTcF greater than 450 msec; history of, or current diagnosis of, liver impairment

**REQUIRED MEDICAL INFORMATION:** Enrollee is at least 6 years of age AND clinical documentation supports Duchenne Muscular Dystrophy diagnosis confirmed by genetic testing AND medical record documents clinical symptoms of DMD such as proximal muscle weakness, Gowers' maneuver, or elevated serum creatinine kinase level AND enrollee must be ambulatory at initiation of therapy as described by: ability to complete 2 Four Stairs Climb tests, with the results within 1 seconds of each other and a mean score of less than 8 seconds and time to rise from floor between 3 and less than 10 seconds

**COVERAGE DURATION:** 6 months

**OTHER CRITERIA:** Therapy will be continued as long as member demonstrates clinical benefit from therapy. Therapy will not be continued if the enrollee demonstrates any of the following: severe drug-related diarrhea, QTcF greater than 500 msec, platelet count less than or equal to  $50 \times 10^9/L$ , white blood cells less than or equal to  $2 \times 10^9/L$ , hemoglobin less than or equal to 8 g/dL

## EMGALITY

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** If used for prevention, the following criteria need to be met:

1) The requested drug is being prescribed for the preventative treatment of migraine in an adult patient

AND

a. The patient has experienced an inadequate treatment response with an 8-week trial of any of the following: antiepileptic drugs, beta-adrenergic blockers, antidepressants

OR

b. The patient received at least 3 months of treatment with the requested drug and the patient has had a reduction in migraine days per month from baseline.

2) Patient has a diagnosis of episodic cluster headache AND BOTH of the following:

a. Patient has had at least 5 cluster headache attacks AND

b. Patient has had at least two cluster periods lasting 7 days to one year and separated by pain-free remission periods of 3 months or more

**COVERAGE DURATION:** Initial approval 3 months, continuation 12 months

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## ENBREL

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile psoriatic arthritis, or juvenile idiopathic arthritis NO prerequisites are required for a diagnoses of ankylosing spondylitis or severe juvenile psoriatic arthritis Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, juvenile psoriatic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids

## EPIDIOLEX

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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**EPOETIN ALFA**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** All indications: excluded if patient has uncontrolled hypertension. In patients with cancer receiving hormonal agents, biologic products, or radiotherapy unless also receiving concomitant myelosuppressive chemotherapy. In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure. In patients with cancer receiving myelosuppressive chemotherapy in whom the anemia can be managed by transfusion. In patients scheduled for surgery who are willing to donate autologous blood. In patients undergoing cardiac or vascular surgery. As a substitute for RBC transfusions in patients who require immediate correction of anemia.

**REQUIRED MEDICAL INFORMATION:** For patients with CKD and NOT on dialysis, consider initiating EPO treatment only when the Hgb level is less than 10g/dl and the following considerations apply: If the Hgb level exceeds 10g/dl, reduce or interrupt the dose of EPO. For patients with CKD and on dialysis initiate the treatment of EPO when the Hgb level is less than 10g/dl. If the Hgb level approaches or exceeds 11 g/dl, reduce or interrupt the dose of EPO. For patients on cancer chemotherapy initiate EPO only if the Hgb is less than 10g/dl and if there is a minimum of 2 additional months of planned chemotherapy. If there is no response as measured by Hgb levels or if RBC transfusions are still required after 8 weeks of therapy and following the completion of chemotherapy, EPO should be discontinued. For HIV patients treated with zidovudine, withhold EPO if Hgb levels exceed 12 g/dl. For patients undergoing elective surgery, Hgb should be greater than 10 but less than 13 g/dl.

**COVERAGE DURATION:** Initial/dose chg 12 wk, Stable-CRF-24 wk, anemia of ca-12 wk, zidov-treated pts with HIV inf-12 wk, reduction of RBC transfusion-6wk

**ERIVEDGE**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

**ERLEADA**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

**ERLOTINIB**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<b>ERIVEDGE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>ERLEADA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>ERLOTINIB</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>EVEROLIMUS</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>FABHALTA</b> <b>PA INDICATION:</b> All FDA- Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>FABRAZYME</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months

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FENTANYL PATCH

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** Current utilization of medication assisted therapy to treat opioid use disorder or alcohol use disorder

**REQUIRED MEDICAL INFORMATION:** Covered if being prescribed for pain associated with cancer, a terminal condition or pain being managed through hospice or palliative care OR for non-cancer pain the patient has a history of a trial with a short acting opioid indicating they can safely take the requested dose AND the patient has been evaluated and will be monitored for the development of opioid use disorder. For the management of chronic severe pain in opioid-tolerant patients who require daily, around the clock, long- term opiate treatment. Opioid tolerant is defined as those taking, for a minimum of 1 week, at least 60mg/day oral morphine, 30mg/day oral oxycodone, 8mg/day oral hydromorphone, 25mg/day oral oxymorphone, 60mg/day oral hydrocodone or an equivalent dose of another opioid.

**COVERAGE DURATION:** Pain with cancer, terminal conditions, hospice/palliative care= 12 months.Non- Cancer Pain= 6 months

**OTHER CRITERIA:** Due to the risks of addiction, abuse, and misuse of opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, fentanyl should be reserved for use in patients for whom at least 2 alternative treatment options (ie. non-opioid analgesics or immediate release opioids) are ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain.

FINTEPLA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

FOTIVDA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

FRUZAQLA

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<b>GATTEX</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>GAVRETO</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>GEFITINIB</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>GILOTRIF</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>GLP-1</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> Use for weight loss alone <b>COVERAGE DURATION:</b> 12 months

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## GROWTH HORMONE

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** Severe respiratory impairment or sleep apnea (Prader-Willi syndrome)

**REQUIRED MEDICAL INFORMATION:** Growth hormone stimulation tests. Children- presenting height must be below 5th percentile. Must be radiographically-documented evidence of delayed bone age.

**PRESCRIBER RESTRICTION:** Endocrinologist, HIV or infectious disease specialist

**COVERAGE DURATION:** 12 months

## HADLIMA

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis NO prerequisites are required for diagnoses of ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis Formulary conventional agents for rheumatoid arthritis, juvenile idiopathic arthritis, or psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine

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<p>HAEGARDA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>HETLIOZ</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>HRM EDITS</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> This Prior Authorization requirement only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that medication benefits outweigh potential risks for this patient.</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>HRM HYPNOTICS</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> Patients who have previously experienced complex sleep behaviors (sleep walking, sleep driving and engaging in other activities while not fully awake) after taking eszopiclone, zaleplon or zolpidem.</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> This Prior Authorization requirement only applies to patients 65 years of age or older. (The American Geriatrics Society identifies the use of this medication as potentially inappropriate in older adults, meaning it is best avoided, prescribed at reduced dosage, or used with caution or carefully monitored.) Prescriber must acknowledge that medication benefits outweigh potential risks for this patient. PA will only be required after a cumulative 90 day supply is filled within the year</p> <p><b>AGE RESTRICTION:</b> PA applies to members 65 years and older</p> <p><b>COVERAGE DURATION:</b> 12 months</p>

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## HUMIRA

PENDING CMS APPROVAL

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** Approval will be 12 weeks for initial use for ulcerative colitis, 12 months for all others

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of plaque psoriasis, rheumatoid arthritis, juvenile idiopathic arthritis, Crohn's disease, or moderate ulcerative colitis NO prerequisites are required for diagnoses of psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, severe ulcerative colitis, or uveitis Formulary conventional agents for rheumatoid arthritis and juvenile idiopathic arthritis, include leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine.

## HYFTOR

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<b>IBRANCE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>ICATIBANT</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>ICLUSIG</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>IDHIFA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>IMATINIB</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>IMBRUVICA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<b>IMKELDI</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>COVERAGE DURATION:</b> 12 months
<b>IMMEDIATE-RELEASE FENTANYL</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>REQUIRED MEDICAL INFORMATION:</b> Must be used for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around the clock opioid therapy for their underlying persistent pain. <b>PRESCRIBER RESTRICTION:</b> Oncologist, hematologist, pain management or palliative care <b>COVERAGE DURATION:</b> 12 months
<b>INBRIJA</b> <b>PA INDICATION:</b> All FDA- Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>REQUIRED MEDICAL INFORMATION:</b> Criteria for approval require ALL of the following: 1. The requested agent will be used for intermittent treatment of OFF episodes in patients with Parkinson’s disease AND 2. Patient is receiving concurrent therapy with carbidopa/levodopa AND 3. Patient will NOT be using a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, tranylcypromine) in combination with, or within 2 weeks of, the requested agent <b>PRESCRIBER RESTRICTION:</b> Neurologist <b>COVERAGE DURATION:</b> 12 months
<b>INGREZZA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>AGE RESTRICTION:</b> 18 years and older <b>PRESCRIBER RESTRICTION:</b> Prescribed by or in consultation with a psychiatrist or neurologist <b>COVERAGE DURATION:</b> Initial approval 3 months. Renewal requests if policy criteria met 6 months

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<b>INLYTA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>INQOVI</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>INREBIC</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>INSULIN MEDICAL SUPPLIES</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>REQUIRED MEDICAL INFORMATION:</b> Criteria for approval require BOTH of the following: 1. The requested medical supply product will be used in the delivery of insulin to the body AND 2. The patient's medication history includes use of insulin within the past 180 days <b>COVERAGE DURATION:</b> 12 months
<b>IQIRVO</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>COVERAGE DURATION:</b> 12 months

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<p>ITOVEBI</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>IWILFIN</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>JAKAFI</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>JAYPIRCA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>JOENJA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>KALYDECO</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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<b>KANJINTI</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
<b>KESIMPTA</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>KISQALI</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>KOSELUGO</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>KRAZATI</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<p>L-GLUTAMINE</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> Sick cell anemia- must be prescribed alongside hydroxyurea unless significant intolerance or contraindication exists AND enrollee has had at least 2 or more painful sickle cell crises within the previous 12 months</p> <p><b>AGE RESTRICTIONS:</b> 5 and older</p> <p><b>PRESCRIBER RESTRICTIONS:</b> Must be prescribed by or in consultation with SCD specialist or a hematologist</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>LAPATINIB</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>LENVIMA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>LIBERVANT</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>LIDOCAINE</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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<p>LIVTENCITY</p> <p><b>PA INDICATION:</b> All FDA- Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>LONG ACTING OPIATES</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> Current utilization of medication assisted therapy to treat opioid use disorder or alcohol use disorder</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> Covered if being prescribed for pain associated with cancer, a terminal condition or pain being managed through hospice or palliative care OR for non-cancer pain the patient has a history of a trial with a short acting opioid indicating they can safely take the requested dose AND the patient has been evaluated and will be monitored for the development of opioid use disorder AND this is a continuation of therapy for a patient who has received an ER opiate for 30+ days OR the patient has received 1 week of an immediate release opiate and has severe continuous pain. For the management of chronic severe pain in opioid-tolerant patients who require daily, around the clock, long- term opiate treatment. Opioid tolerant is defined as those taking, for a minimum of 1 week, at least 60mg/day oral morphine, 30mg/day oral oxycodone, 8mg/day oral hydromorphone, 25mg/day oral oxymorphone, 60mg/day oral hydrocodone or an equivalent dose of another opioid.</p> <p><b>COVERAGE DURATION:</b> Pain with cancer, terminal conditions, hospice/palliative care= 12 months. Non- Cancer Pain= 6 months</p> <p><b>OTHER CRITERIA:</b> Extended release morphine should be reserved for when at least 2 alternative treatment options (ie.non-opioid analgesics or immediate release opioids) are ineffective, not tolerated or would be otherwise inadequate to provide sufficient management of pain.</p>
<p>LONSURF</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>LORBRENA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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LUMAKRAS <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
LUMIZYME <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
LYNPARZA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
LYTGOBI <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
MAVYRET <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>AGE RESTRICTION:</b> 3 years and older <b>PRESCRIBER RESTRICTION:</b> Gastroenterologist, Hepatologist, HIV or infectious disease specialist <b>COVERAGE DURATION:</b> Approval duration will be applied consistently with AASLD-IDSA guidance

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<b>MEKINIST</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>MEKTOVI</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>MIFEPRISTONE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>MIGLUSTAT</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>MODAFINIL</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>REQUIRED MEDICAL INFORMATION:</b> Criteria for approval require BOTH of the following: 1. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND 2. Patient will NOT be using the requested agent in combination with another target agent (i.e., armodafinil) <b>AGE RESTRICTIONS:</b> Patient is 17 years of age or over <b>COVERAGE DURATION:</b> 12 months

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<b>MVASI</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
<b>NAGLAZYME</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
<b>NERLYNX</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>NEXLETOL</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>NEXLIZET</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>NEXVIAZYME</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<p>NINLARO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>NUBEQA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>NUCALA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> Acute bronchospasm or status asthmaticus</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> Severe asthma as add-on maintenance treatment. For diagnosis of severe asthma the enrollee must have an eosinophilic phenotype characterized by: a. Sputum eosinophil count of 3% or more OR blood eosinophil count greater than 150 cells/mcL within 6 weeks of starting therapy OR greater than 300 cells/mcL in the previous 12 months. Add-on maintenance treatment for adults with chronic rhinosinusitis with nasal polyps. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis. Treatment of adult and pediatric patients with hypereosinophilic syndrome for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.</p> <p><b>AGE RESTRICTIONS:</b> Eosinophilic Granulomatosis with Polyangiitis ( Churg-Strauss Syndrome) 18 years and older, Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. Hypereosinophilic syndrome: 12 years and older, chronic rhinosinusitis with nasal polyps: 18 years and older.</p> <p><b>PRESCRIBER RESTRICTIONS:</b> Prescribed by or in consultation with a pulmonologist, allergist, immunologist, rheumatologist, hematologist, otolaryngologist</p> <p><b>COVERAGE DURATION:</b> 12 months</p> <p><b>OTHER CRITERIA:</b> The enrollee must not have had a parasitic infection within the last 6 months. Approval for severe asthma will be contingent on the continued use of standard of care for asthma (inhaled corticosteroids and additional controlled medications such as long acting beta agonists). Criteria for renewal approval require that the patient has been previously approved for the requested agent AND has the appropriate FDA approved diagnosis AND has had clinical benefit with the requested agent AND the requested dose is within FDA labeled dosing for the requested indication.</p>

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<p>NUEDEXTA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>NUPLAZID</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>NURTEC</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> If used for prevention the following criteria need to be met: 1) The requested drug is being prescribed for the preventative treatment of migraine in an adult patient AND a) The patient has experienced an inadequate treatment response with an 8 week trial of any of the following: antiepileptic drugs, beta-adrenergic blockers, antidepressants OR b) the patient received at least 3 months of treatment with the requested drug and the patient has had a reduction in migraine days per month from baseline. If used for acute treatment, the following criteria need to be met: the patient has a history of 2 to 8 migraines per month with moderate to severe headache pain in the previous 3 months AND the patient has had failure with a generic formulary triptan agent at maximally indicated dose unless contraindicated or pt has an intolerance or hypersensitivity</p> <p><b>COVERAGE DURATION:</b> Initial approval 3 months, continuation 12 months</p>
<p>ODOMZO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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OFEV

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require the following:

1. ONE of the following:

A. BOTH of the following:

- i. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
- ii. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD) OR

B. BOTH of the following:

- i. Patient has a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) AND
- ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT) or chest radiography scans OR

C. BOTH of the following:

- i. Patient has a diagnosis of chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND
- ii. Patient's diagnosis has been confirmed on high-resolution computed tomography (HRCT)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has a diagnosis of ONE of the following:

- A. Idiopathic pulmonary fibrosis (IPF) OR
- B. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) OR
- C. Chronic fibrosing interstitial lung disease (ILD) with a progressive phenotype AND

3. Patient has had clinical benefit with the requested agent

**PRESCRIBER RESTRICTIONS:** Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**COVERAGE DURATION:** 12 months

OGSIVEO

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<p>OJEMDA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>OJJAARA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>ONTRUZANT</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>ONUREG</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>OPFOLDA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>ORGOVYX</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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ORKAMBI

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

ORSERDU

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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## OTEZLA

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Criteria for initial approval require BOTH of the following: 1. ONE of the following: A. BOTH of the following: i. Patient has ONE of the following diagnoses: 1. Plaque psoriasis OR 2. Active psoriatic arthritis AND ii. ONE of the following: 1. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR 2. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR 3. Patient's medication history indicates use of a biologic immunomodulator agent for the same FDA labeled indication OR 4. Patient has tried and had an inadequate response to at least ONE conventional prerequisite agent for the requested indication OR 5. Patient has an intolerance or hypersensitivity to at least ONE conventional prerequisite agent for the requested indication OR 6. Patient has an FDA labeled contraindication to at least ONE conventional prerequisite agent for the requested indication OR B. Patient has a diagnosis of oral ulcers associated with Behcet's disease (BD) AND 2. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has ONE of the following diagnoses: A. Plaque psoriasis OR B. Active psoriatic arthritis OR C. Oral ulcers associated with Behcet's disease (BD) AND 3. Patient has had clinical benefit with the requested agent (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Formulary conventional agent required for diagnoses of plaque psoriasis or active psoriatic arthritis Formulary conventional agents for plaque psoriasis include cyclosporine, methotrexate, tazarotene, topical calcitriol, or topical corticosteroids Formulary conventional agents for active psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine NO prerequisites are required for a diagnosis of oral ulcers associated with Behcet's disease (BD)

## OXERVATE

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**AGE RESTRICTIONS:** Ages 2 and older

**PRESCRIBER RESTRICTIONS:** Ophthalmologist

**COVERAGE DURATION:** 8 weeks

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<b>PEGASYS</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
<b>PEMAZYRE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>PHENYLBUTYRATE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>PIQRAY</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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PIRFENIDONE

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require BOTH of the following:

1. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
2. Patient has no known explanation for interstitial lung disease (ILD) or pulmonary fibrosis (e.g., radiation, drugs, metal dusts, sarcoidosis, or any connective tissue disease known to cause ILD)

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND
2. Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) AND
3. Patient has had clinical benefit with the requested agent

**PRESCRIBER RESTRICTIONS:** Prescriber is a specialist in the area of the patient's diagnosis (e.g., pathologist, pulmonologist, radiologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis

**COVERAGE DURATION:** 12 months

POMALYST

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

POMBILITI

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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#### PROLIA

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** For osteoporosis treatment, patients must be at high risk for osteoporotic fracture defined as a previous history of osteoporosis related fracture or a T score of less than or equal to 2.5, or a T-score between -1 and -2.5 with a 10 year hip fracture probability greater than 3% or 10-year major osteoporosis-related fracture probability greater than 20% based on FRAX score and must show failure of six months or more of therapy with a bisphosphonate defined as an osteoporotic fracture while on therapy or a significant reduction in BMD while on therapy, or the patient has a contraindication to bisphosphonates. Contraindications to bisphosphonates include renal insufficiency with a eGFR or estimated creatinine clearance of less than 35 ml per minute or a contraindication to oral bisphosphonate because of an inability to remain upright for the required 30 to 60 minutes following an oral dose, or esophageal abnormalities that delay esophageal emptying, Barrett's esophagus, or esophageal ulceration. For use to increase bone mass in women at high risk for fracture who are receiving adjuvant aromatase inhibitor therapy for breast cancer, must demonstrate having a baseline BMD T score of -1 to -2.5 at the lumbar spine, total hip, or femoral neck. For use to increase bone mass in men at high risk for fracture who are receiving androgen deprivation therapy for nonmetastatic prostate cancer, must demonstrate having a BMD T score at the lumbar spine, total hip, or femoral neck between -1 and -4 or having a history of an osteoporotic fracture.

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Should be administered by a healthcare professional. Dosing is a subcutaneous injection of 60mg every 6 months.

#### PROMACTA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

#### PULMONARY ARTERIAL HYPERTENSION

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**PRESCRIBER RESTRICTIONS:** Cardiologist, Pulmonologist

**COVERAGE DURATION:** 12 months

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<p>PROMACTA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>PULMONARY ARTERIAL HYPERTENSION</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>PRESCRIBER RESTRICTIONS:</b> Cardiologist, Pulmonologist</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>QINLOCK</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>QUININE SULFATE</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>QULIPTA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> The requested drug will be covered when the following criteria are met: 1) The requested drug is being prescribed for the preventative treatment of migraine in an adult patient AND a) The patient has experienced an inadequate treatment response with an 8 week trial of any of the following: antiepileptic drugs, beta-adrenergic blockers, antidepressants OR b) the patient received at least 3 months of treatment with the requested drug and the patient has had a reduction in migraine days per month from baseline</p> <p><b>COVERAGE DURATION:</b> Initial approval 3 months, continuation 12 months</p>

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REMICADE

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** 12 months

RENFLEXIS

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** 12 months

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REPATHA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:**

1. Patient has ONE of the following:

- A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following:
  - i. Genetic confirmation of one mutant allele at the LDLR, Apo-B, PCSK9, or 1/LDLRAP1 gene OR
  - ii. History of LDL-C greater than 190 mg/dL (greater than 4.9 mmol/L) (pretreatment) OR
  - iii. Patient has clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthoma, or xanthelasma) OR
  - iv. Patient has “definite” or “possible” familial hypercholesterolemia as defined by the Simon Broome criteria OR
  - v. Patient has a Dutch Lipid Clinic Network criteria score of greater than 5 OR
  - vi. Patient has a treated low-density lipoprotein cholesterol (LDL-C) level 100 mg/dL or greater after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy OR
  - vii. History of LDL-C of 160 mg/dL (4.1 mmol/L) or greater (pretreatment) in a pediatric patient OR
- B. A diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ONE of the following:
  - i. Genetic confirmation of two mutant alleles at the LDLR, Apo-B, PCSK9, or LDLRAP1 gene OR
  - ii. History of untreated LDL-C greater than 500 mg/dL (greater than 13 mmol/L) or treated LDL-C 300 mg/dL or greater (7.76 mmol/L or greater) OR
  - iii. Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas, or xanthelasma) OR
- C. A diagnosis of established cardiovascular disease [angina pectoris, coronary heart disease, myocardial infarction, transient ischemic attacks, cerebrovascular disease (CeVD) or peripheral vascular disease (PVD) or after coronary revascularization or carotid endarterectomy] AND the requested agent will be used to reduce the risk of myocardial infarction, stroke, and coronary revascularization OR
- D. A diagnosis of primary hyperlipidemia (not associated with HeFH, HoFH, or established cardiovascular disease) OR

Initial criteria continues: see Other Criteria

**PRESCRIBER RESTRICTIONS:** The agent was prescribed by, or in consultation with, a cardiologist, an endocrinologist, and/or a physician who focuses in the treatment of cardiovascular (CV) risk management and/or lipid disorders

**COVERAGE DURATION:** 12 months

CONTINUED...

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REPATHA (CONTINUED)

**OTHER CRITERIA:**

E. Patient has another indication that is supported in CMS approved compendia for the requested agent AND

3. ONE of the following:

A. Patient has tried and had an inadequate response to a high-intensity statin (i.e., rosuvastatin 20-40 mg or atorvastatin 40-80 mg) OR

B. Patient has an intolerance to TWO different statins OR

C. Patient has an FDA labeled contraindication to a statin AND

4. Patient will NOT be using the requested agent in combination with another PCSK9 agent

Criteria for renewal approval require ALL of the following:

1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND

2. Patient has an FDA labeled indication or an indication that is supported in CMS approved compendia for the requested agent AND

3. Patient has had clinical benefit with the requested agent AND

4. Patient will NOT be using the requested agent in combination with another PCSK9 agent

RETEVMO

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

REVLIMID

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

REVUFORJ

**PA INDICATION:** All FDA- Approved Indications

**COVERAGE DURATION:** 12 months

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## REZDIFFRA

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:**

- Member has evidence of fibrosis stage 0, 1, or 4 (cirrhosis)
- Member has any other causes of chronic liver disease other than non-cirrhotic NASH

**REQUIRED MEDICAL INFORMATION:**

- Member has evidence of NASH and moderate to advanced liver fibrosis (stage 2 or 3) as determined by one of the following:
  - o Liver biopsy within previous six months OR
  - o At least two of the following non-invasive assessments, in accordance with 2023 AASLD NASH/MASH guidance
    - Fibrosis-4 index (FIB-4) • Vibration-controlled Transient Elastography (VCTE) • Enhanced Liver Fibrosis (ELF)
    - Magnetic Resonance Elastography (MRE) • Corrected T1 (cT1) AND
  - o Histologic evidence supporting the presence of all 3 key histological features of MASH: steatosis, lobular inflammation, and hepatocyte ballooning
- Provider must rule out secondary causes and/or diseases associated with hepatic steatosis, including:
  - o Excess alcohol - defined as significant ongoing or recent<sup>†</sup> alcohol consumption defined as [AASLD guidance]:
    - Greater than or = to 21 standard drinks\* on average per week for men or • Greater than or =to 14 standard drinks on average per week for women
  - \*standard drink is any drink that contains about 14g of pure alcohol <sup>†</sup>more than 3 consecutive months within 1 year
  - o Medications (e.g., amiodarone, methotrexate, tamoxifen, corticosteroids, irinotecan, 5-FU)
  - o Starvation/malnutrition
  - o Parenteral nutrition
  - o Hepatitis C (particularly genotype 3)
  - o Wilson disease
  - o Lipodystrophy
  - o Abetalipoproteinemia
  - o Reye syndrome
  - o Pregnancy associated: HELLP Syndrome or acute fatty liver of pregnancy
  - o Hypobetalipoproteinemia
  - o LAL deficiency
  - o Celiac disease

**PRESCRIBER RESTRICTIONS:** Board-certified hepatologist or gastroenterologist

**COVERAGE DURATION:** Initial approval: 6 months. Continuation approval: 6 months

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REZLIDHIA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

REZUROCK

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

RIABNI

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** 12 months

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## RINVOQ

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. ONE of the following: i. BOTH of the following: a. Patient has an FDA labeled indication other than moderate to severe atopic dermatitis for the requested agent AND b. ONE of the following: 1. Patient's medication history indicates use of preferred TNF agent(s) OR 2. Patient has an intolerance or hypersensitivity to preferred TNF agent(s) OR 3. Patient has an FDA labeled contraindication to preferred TNF agent(s) OR 4. The request is for an FDA labeled indication that is not covered by preferred TNF agent(s) OR ii. Patient has a diagnosis of moderate to severe atopic dermatitis AND ONE of the following: a. Patient's medication history indicates use of TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR b. Patient has an intolerance or hypersensitivity to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication OR c. Patient has an FDA labeled contraindication to TWO conventional prerequisite agents (i.e., ONE formulary topical corticosteroid AND ONE formulary topical calcineurin inhibitor) for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication Use of ONE preferred TNF (Enbrel, Hadlima, or Humira) is required for diagnoses of ankylosing spondylitis, rheumatoid arthritis, adult psoriatic arthritis, or juvenile idiopathic arthritis Use of ONE preferred TNF (Hadlima or Humira) is required for diagnoses of ulcerative colitis or Crohn's disease Use of TWO conventional prerequisite agents are required for diagnosis of moderate to severe atopic dermatitis NO preferred TNF agents are required for diagnoses of pediatric psoriatic arthritis or non-radiographic axial spondyloarthritis

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RIVFLOZA <b>PA INDICATION:</b> All FDA- Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ROZLYTREK <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
RUBRACA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
RUXIENCE <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
RYDAPT <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
SAPROPTERIN <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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SCEMBLIX

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

SIGNIFOR

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

SKYCLARYS

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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## SKYRIZI

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR E. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of Crohn's disease, plaque psoriasis, or psoriatic arthritis. Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, or mercaptopurine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids. Formulary conventional agents for psoriatic arthritis include leflunomide, methotrexate, or sulfasalazine

## SOHONOS

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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SORAFENIB

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

SPRYCEL

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**AGE RESTRICTIONS:** Approved for those 18 years of age or older for Ph+CML-CP, PH+ ALL resistant or intolerant to prior therapy, chronic, accelerated or myeloid or lymphoid blast phase PH+CML with resistance or intolerance to prior therapy including imatinib, Approved for those 1 year of age or older in pediatric patients with Ph+ CML in chronic phase and for pediatric patients with newly diagnosed Ph+ ALL in combination with chemotherapy

**COVERAGE DURATION:** 12 months

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## STELARA

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 4. The requested dose is within FDA labeled dosing for the requested indication Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of psoriatic arthritis, plaque psoriasis, moderate ulcerative colitis, or Crohn's disease NO prerequisites are required for diagnosis of severe ulcerative colitis Formulary conventional agents for psoriatic arthritis include cyclosporine, leflunomide, methotrexate, or sulfasalazine Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for Crohn's disease include methotrexate, sulfasalazine, corticosteroids, azathioprine, mercaptopurine Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, mercaptopurine

## STIVARGA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<p>SUNITINIB</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>SYMDEKO</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>SYMPAZAN</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>TABRECTA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>TADALAFIL</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> Treatment for erectile dysfunction</p> <p><b>COVERAGE DURATION:</b> 12 months</p>

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#### TAFAMIDIS

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** As limited by FDA labeling

**REQUIRED MEDICAL INFORMATION:** Diagnosis, pertinent lab/diagnostic tests, including tests confirming presence of TTR amyloid in cardiac tissue such as 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein

**AGE RESTRICTIONS:** Patient age must be consistent with the FDA approval for the stated diagnosis.

**PRESCRIBER RESTRICTIONS:** Must be prescribed by a specialist experienced in the diagnosis of Transthyretin-mediated Amyloidosis (ATTR-CM), such as a cardiologist.

**COVERAGE DURATION:** One Year

**OTHER CRITERIA:** Covered for patients with a diagnosis of cardiomyopathy of wild-type (wtATTR-CM) or Hereditary Transthyretin-mediated Amyloidosis (hATTR-CM). Patient must have a medical history of NYHA class I-III heart failure with at least one prior hospitalization for heart failure or clinical evidence of heart failure requiring treatment with a diuretic for improvement. Evidence of cardiac involvement seen on echocardiography and/or cardiac magnetic imaging, such as thickened left ventricle wall or septum, must be provided. Presence of TTR amyloid in cardiac tissue must be confirmed via 99m Technetium-labeled pyrophosphate cardiac imaging test results (nuclear scintigraphy) positive for TTR amyloid or via genetic testing/next-generation sequencing confirming a variant TTR genotype and/or TTR precursor protein correlated with amyloid deposits identified on cardiac biopsy. Upon recertification, there must be documentation that the patient continues to obtain clinical benefit from the therapy. Requests for non-FDA approved indications will be evaluated according to the Medicare statutory off-label use requirements.

#### TAFINLAR

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

#### TAGRISSO

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<p><b>TALZENNA</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p><b>TASIGNA</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> Adults with Ph+CML in CP or accelerated phase: resistant to or intolerant to prior therapy with imatinib. Peds with Ph+CML in CP: resistant to or intolerant to prior tyrosinekinase inhibitor (TKI) therapy. Adult and pediatric patients with newly diagnoses Philadelphia chromosome positive CML- no prior therapy required</p> <p><b>AGE RESTRICTIONS:</b> Newly diagnosed Ph+CML in CP: Approved for adults and pediatric patients greater or equal to 1 year of age. Accelerated Phase (AP) and Chronic Phase (CP) Ph+CML resistant/intolerant to prior therapy that included imatinib: Approved for those 18 years of age or older. Ph+CML-CP and CML-AP resistant/intolerant to prior TKI therapy: Approved for adults and pediatric patients greater or equal to 1 year of age</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p><b>TAVNEOS</b></p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p><b>TAZVERIK</b></p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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TEPMETKO <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
TETRABENAZINE <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>AGE RESTRICTIONS:</b> 18 years and older <b>PRESCRIBER RESTRICTIONS:</b> Prescribed by or in consultation with a psychiatrist or neurologist <b>COVERAGE DURATION:</b> Initial approval 3 months. Renewal requests if policy criteria met 6 months
THALOMID <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
TIBSOVO <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
TRAZIMERA <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months

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## TREMFYA

PENDING CMS APPROVAL

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** FDA labeled contraindications to the requested agent

**REQUIRED MEDICAL INFORMATION:** Criteria for initial approval require ALL of the following: 1. Patient has an FDA labeled indication for the requested agent AND 2. ONE of the following: A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR B. Prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR C. Patient's medication history indicates use of another biologic immunomodulator agent for the same FDA labeled indication OR D. Patient's diagnosis does NOT require a conventional prerequisite agent OR E. Patient's medication history indicates use of ONE formulary conventional prerequisite agent for the requested indication OR F. Patient has an intolerance or hypersensitivity to at least ONE formulary conventional prerequisite agent for the requested indication OR G. Patient has an FDA labeled contraindication to at least ONE formulary conventional prerequisite agent for the requested indication AND 3. Patient does NOT have any FDA labeled contraindications to the requested agent AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication. Criteria for renewal approval require ALL of the following: 1. Patient has been previously approved for the requested agent through the plan's Prior Authorization criteria AND 2. Patient has an FDA labeled indication for the requested agent AND 3. Patient has had clinical improvement (slowing of disease progression or decrease in symptom severity and/or frequency) AND 4. Patient will NOT be using the requested agent in combination with another biologic immunomodulator AND 5. The requested dose is within FDA labeled dosing for the requested indication. See other criteria for prerequisite agents.

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:** Use of ONE conventional prerequisite agent is required for diagnoses of plaque psoriasis or moderate ulcerative colitis. NO prerequisites are required for diagnosis of psoriatic arthritis or severe ulcerative colitis. Formulary conventional agents (topical or systemic) for plaque psoriasis include acitretin, calcipotriene, methotrexate, tazarotene, or topical corticosteroids Formulary conventional agents for moderate ulcerative colitis include 5-aminosalicylates, corticosteroids, azathioprine, or mercaptopurine.

## TRIKAFTA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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<p>TRUQAP</p> <p><b>PA INDICATION:</b> All FDA- Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>TUKYSA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>TURALIO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>TYSABRI</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>UBRELVY</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>REQUIRED MEDICAL INFORMATION:</b> The requested drug is being prescribed for the acute treatment of migraine in an adult patient AND the patient has a history of 2 to 8 migraines per month with moderate to severe headache pain in the previous 3 months AND the patient has had failure with one formulary triptan agent at maximally indicated dose unless contraindicated or pt has an intolerance or hypersensitivity</p> <p><b>COVERAGE DURATION:</b> Initial 3 months, renewals 12 months</p>

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<b>VALCHLOR</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VANFLYTA</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VENCLEXTA</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VERZENIO</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VIJOICE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<b>VITRAKVI</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VIZIMPRO</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VONJO</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VOQUEZNA</b> <b>PA INDICATION:</b> All FDA- Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>VORICONAZOLE</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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<p>VOSEVI</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>AGE RESTRICTIONS:</b> 18 years and older</p> <p><b>PRESCRIBER RESTRICTIONS:</b> Gastroenterologist, Hepatologist, HIV or infectious disease specialist</p> <p><b>COVERAGE DURATION:</b> Approval duration will be applied consistently with AASLD-IDSA guidance</p> <p><b>OTHER CRITERIA:</b> Omeprazole 20mg can be administered with Vosevi. Use with other proton pump inhibitors has not been studied</p>
<p>VOTRIENT</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>VOYDEYA</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>VOWST</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>WAINUA</p> <p><b>PA INDICATION:</b> All FDA- Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>

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<b>WELIREG</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>WINREVAIR</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>COVERAGE DURATION:</b> 12 months
<b>XALKORI</b> <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
<b>XDEMVY</b> <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 3 months

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## XELJANZ

**PA INDICATION:** All FDA-Approved Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:**

1. The patient has an FDA labeled indication for the requested agent AND
2. ONE of the following:
  - A. There is evidence of a claim that the patient is currently being treated with the requested agent within the past 90 days OR
  - B. The prescriber states the patient is currently being treated with the requested agent AND provided clinical justification to support that the patient is at risk if therapy is changed OR
  - C. ONE of the following:
    - i. The patient's medication history indicates use of preferred TNF agent(s)\* OR
    - ii. The patient has an intolerance or hypersensitivity to preferred TNF agent(s)\* OR
    - iii. The patient has an FDA labeled contraindication to preferred TNF agent(s)\* AND
3. The patient does NOT have any FDA labeled contraindications to the requested agent AND
4. The patient will NOT be using the requested agent in combination with another biologic immunomodulator AND
5. The requested dose is within FDA labeled dosing for the requested indication

**COVERAGE DURATION:** 12 months

**OTHER CRITERIA:**

Xeljanz (tofacitinib tablet):

Use of ONE preferred TNF (Enbrel, Hadlima or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, juvenile idiopathic arthritis, or ankylosing spondylitis.

Use of ONE preferred TNF (Hadlima or Humira) is required for diagnosis of ulcerative colitis.

Xeljanz (tofacitinib solution):

Use of ONE preferred TNF (Enbrel, Hadlima or Humira) is required for diagnosis of juvenile idiopathic arthritis.

Xeljanz XR (tofacitinib extended release):

Use of ONE preferred TNF (Enbrel, Hadlima or Humira) is required for diagnoses of psoriatic arthritis, rheumatoid arthritis, or ankylosing spondylitis.

Use of ONE preferred TNF (Hadlima or Humira) is required for diagnosis of ulcerative colitis

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XERMELO

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

XGEVA

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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## XOLAIR

**PA INDICATION:** All FDA- Approved Indications

**EXCLUSION CRITERIA:** None

**REQUIRED MEDICAL INFORMATION:** Asthma: Documented evidence of reversible airway disease, IgE level greater or equal to 30 and less than or equal to 700 IU/ ml for ages greater than or equal to 12 years old, for patients 6 to 12 years old IgE level greater or equal to 30 and less than or equal to 1300 IU/ ml evidence of specific allergic sensitivity by a positive skin or blood test for specific IgE. Chronic spontaneous urticaria-CSU-documented evidence of daily or almost daily wheals and itching for at least 6 weeks with no obvious cause. Nasal Polyps: enrollee has received treatment with an intranasal corticosteroid for at least 8 weeks prior to requesting Xolair AND enrollee has at least 2 of the following 3 symptoms: nasal congestion or obstruction, loss of smell, nasal discharge. IgE-mediated food allergy: Must have multiple IgE mediated food allergies confirmed by one of the following (1 or 2): 1. Oral food challenge (OFC) AND a. Skin prick test wheal greater than or equal to 3mm OR IgE level commensurate with food allergen OR 2. Dx of IgE mediated food allergy NOT confirmed by OFC, AND a. Medical documentation providing history of anaphylactic reaction that required clinical intervention (urgent care or ER visit) b. Skin prick test wheal greater than or equal to 8mm AND IgE level commensurate with food allergen. Medication is being used in conjunction with a food avoidant diet to the particular allergens.

**AGE RESTRICTIONS:** Asthma: Approved for those 6 years of age or older. CSU: Approved for those 12 years of age or older. Nasal Polyps: 18 years and older. IgE-Mediated Food Allergy: Age 1 and older

**PRESCRIBER RESTRICTIONS:** Prescribed by or in consultation with an allergist, immunologist, pulmonologist or dermatologist

**COVERAGE DURATION:** Asthma, CIU, Nasal polyps 12 months, IgE mediated food allergy- 6 months initial, 12 months renewal

**OTHER CRITERIA:** Asthma: Inadequately controlled on medium-dose inhaled corticosteroid. CIU-must have documented trial and failure or inadequate control for at least 3 months of therapy of H1 with or without H2 antihistamines unless intolerant or contraindicated. Dose is administered once every 28 days. Asthma and CIU- Patient must be instructed regarding the signs and symptoms of anaphylaxis. IgE mediated food allergy- multiple food allergies include peanut and at least 2 other trial specific foods (cashew, milk, egg, walnut, wheat, hazelnut). Anaphylactic symptoms include vomiting, urticaria, angio edema, rhino-conjunctivitis, asthma etc). Clinical symptoms requiring intervention are evident in a few minutes to upwards of 2 hours. Continuation criteria: After initial 4-5 months of therapy member completes OFC and has the following findings (dependent on allergens): a. Ingestion of peanut protein in a single dose of 600mg or more without dose limiting symptoms, b. Ingestion of cashew, milk and/or egg in single doses of at least 1000mg each without dose limiting symptoms. Member is continuing to demonstrate clinical benefit as per provider documentation and clinical assessment. If the medication is being obtained at a retail pharmacy it may be covered under Part D if the following conditions are satisfied: A physician is administering the medication and he/she agree to accept brown bagging of the medication and understands that the member will obtain the medication from a pharmacy and have it in their possession until it is delivered to the physician office or clinic for administration (ie pharmacy ships drug to member). If the medication is shipped from the specialty pharmacy directly to the office/clinic it will be covered as a Part B benefit.

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<p>XOLREMDI</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> 12 months</p>
<p>XOSPATA</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>XPOVIO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>XTANDI</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>XYREM</p> <p><b>PA INDICATION:</b> All FDA-Approved Indications</p> <p><b>EXCLUSION CRITERIA:</b> None</p> <p><b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended</p>
<p>ZARXIO</p> <p><b>PA INDICATION:</b> All Medically-Accepted Indications</p> <p><b>EXCLUSION CRITERIA:</b> Treatment of acute afebrile neutropenia.</p> <p><b>COVERAGE DURATION:</b> 3 months</p>

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ZEJULA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ZELBORAF <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ZILBRYSQ <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ZIRABEV <b>PA INDICATION:</b> All FDA-Approved Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> 12 months
ZOLINZA <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended
ZTALMY <b>PA INDICATION:</b> All Medically-Accepted Indications <b>EXCLUSION CRITERIA:</b> None <b>COVERAGE DURATION:</b> Indefinitely until plan enrollment ended

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**ZYDELIG**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

**ZYKADIA**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

**ZYPREXA RELPREVV**

**PA INDICATION:** All Medically-Accepted Indications

**EXCLUSION CRITERIA:** None

**COVERAGE DURATION:** Indefinitely until plan enrollment ended

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