

2022 Priority Health Medicare Prior Authorization Criteria

An alphabetical index by drug name appears after the drug criteria listings.

Last updated: December 2022

abiraterone acetate

Products Affected

abiraterone acetate oral tablet 250 mg, 500 mg

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ACTEMRA ACTPEN

Products Affected

ACTEMRA ACTPEN

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Patient must not be receiving Actemra in combination with another biologic drug. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic DMARD(e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ACTEMRA SYRINGE

Products Affected

ACTEMRA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Patient must not be receiving Actemra in combination with another biologic drug. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic DMARD(e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ACTHAR

Products Affected

ACTHAR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial-in accordance with FDA label or max of 3 mos. if unspecified in label. Continuation-1 year. |
| Other Criteria | For all FDA-approved indications except infantile spasms, must have a therapeutic trial of parenteral glucocorticoid. Supporting documentation for all drug trials is required demonstrating inadequate response, intolerance, or FDA labeled contraindication to therapy. For acute exacerbations of multiple sclerosis: one month trial of oral glucocorticoid. For nephrotic syndrome associated with lupus erythematosus, systemic lupus erythematosus, and inflammatory ocular disorders: one month trial of an immunosuppressant (e.g. cyclophosphamide, tacrolimus, mycophenolate mofetil, methotrexate, azathioprine). For adjunctive therapy for short-term administration rheumatic disease: 12-weeks trial of two different biologic therapies. For systemic dermatomyositis (polymyositis): 12-week trials with rituximab and IVIG. Continuation of previously authorized therapy requires demonstrated clinical benefit. Quantity limited to dosage as supported by the FDA-approved label. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ACTIMMUNE

Products Affected

ACTIMMUNE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | Patient's body surface area (BSA) |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ADASUVE

Products Affected

ADASUVE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must first try both olanzapine and loxapine. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ADEMPAS

Products Affected

ADEMPAS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For chronic thromboembolic pulmonary hypertension, must be in World Health Organziation Group 4. For pulmonary arterial hypertension, must be in World Health Organization Group 1, and patients not previously treated for pulmonary aterial hypertension must first try sildenafil (generic Revatio). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AIMOVIG

Products Affected

AIMOVIG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy. |
| Required Medical Information | Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist. |
| Coverage Duration | One year |
| Other Criteria | For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

AJOVY

Products Affected

AJOVY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy |
| Required Medical Information | Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist. |
| Coverage Duration | One year |
| Other Criteria | For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ALECENSA

Products Affected

ALECENSA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ALUNBRIG

Products Affected

ALUNBRIG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AMVUTTRA

Products Affected

AMVUTTRA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Tegsedi, Onpattro). |
| Required Medical Information | Medical records supporting the request must be provided - AND - Must have documentation of a transthyretin (TTR) mutation (e.g., V30M) - AND - Must have documentation of a baseline polyneuropathy disability (PND) score less than or equal to IIIb and/or baseline FAP Stage 1 or 2. |
| Age Restrictions | Must be at least 18 years of age. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year initial and reauthorization. Dose must align with the FDA-approved labeling. |
| Other Criteria | Must have documentation of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.) - AND - Patient has not had a liver transplant - AND - For reauthorization, must have a positive clinical response to Amvuttra compared to baseline (e.g., improved neuropathy symptoms, motor function, quality of life, slowing of disease progression). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ARALAST

Products Affected

 ARALAST NP INTRAVENOUS SOLUTION RECONSTITUTED 1000 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry) |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ARCALYST

Products Affected

ARCALYST

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ARIKAYCE

Products Affected

ARIKAYCE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For initial review, sputum culture supporting the diagnosis of Mycobacterium avium complex (MAC) lung disease must be submitted. For continuation, documentation of negative sputum culture obtained within the last 30 days must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with an infectious disease specialist. |
| Coverage Duration | Initial approval for 6 months. Continuation for 12 months. |
| Other Criteria | For initial review, documentation of failure to obtain a negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

armodafinil

Products Affected

armodafinil

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AUBAGIO

Products Affected

AUBAGIO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

Auryxia

Products Affected

AURYXIA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis, must first try and fail calcium acetate. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

AUSTEDO

Products Affected

 AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with tetrabenazine, Ingrezza, a monoamine oxidase inhibitor (MAOI), or reserpine. |
| Required Medical Information | For diagnosis of tardive dyskinesia (TD), baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval for 6 months, continuation for one year. |
| Other Criteria | For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For continuation, documentation of improvement in chorea symptoms for Huntingtons disease or improvement in AIMS score compared to baseline for TD. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AVEED

Products Affected

AVEED

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pretreatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an inability to improve symptoms or condition) with a generic injectable - AND - generic topical testosterone therapy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AVONEX

Products Affected

- AVONEX PEN INTRAMUSCULAR AUTO-INJECTOR KIT
- AVONEX PREFILLED INTRAMUSCULAR PREFILLED SYRINGE KIT

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

AYVAKIT

Products Affected

AYVAKIT

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BALVERSA

Products Affected

BALVERSA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BENLYSTA

Products Affected

• BENLYSTA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used with another biologic drug or Lupkynis. |
| Required Medical Information | For SLE, must have a SELENA-SLEDAI score of 6 or more before starting Benlysta AND either an anti-dsDNA antibody greater than 30 IU/ml or ANA greater than 1:80. For LN, must have a confirmed diagnosis of SLE - AND - a kidney biopsy confirming class 3, 4, and/or 5 disease. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a specialist in treating the condition or have consulted with a specialist. |
| Coverage Duration | One year |
| Other Criteria | FOR SLE: Must be taking two of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, and/or hydroxychloroquine. FOR LUPUS NEPHRITIS: Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid). FOR CONTINUATION OF PREVIOUSLY APPROVED SLE REQUESTS: Must have evidence of clinical improvement since starting Benlysta. FOR CONTINUATION OF PREVIOUSLY APPROVED LUPUS NEPHRITIS REQUESTS: Must have evidence of clinical improvement including improved or stable eGFR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

BESREMI

Products Affected

BESREMI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Baseline Complete blood count (CBC). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must trial and fail hydroxyurea (defined as an intolerance and/or persistence or recurrence of disease) - AND - Prescriber must follow dose recommendations per FDA-approved labeling. Once hematologic stability has been achieved with Besremi for one year, dosing interval should be expanded to every 4 weeks. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

bexarotene

Products Affected

bexarotene

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BEXAROTENE GEL

Products Affected

bexarotene

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must first try tazarotene. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BOSULIF

Products Affected

 BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BRAFTOVI

Products Affected

• BRAFTOVI ORAL CAPSULE 75 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have documentation of BRAF V600 mutation status. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

BRUKINSA

Products Affected

• BRUKINSA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CABOMETYX

Products Affected

CABOMETYX

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CALQUENCE

Products Affected

CALQUENCE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CAPLYTA

Products Affected

CAPLYTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have tried and failed (defined as taking the medication as prescribed without an adequate response or with intolerance) two of the following generic atypical antipsychotics: aripiprazole, ziprasidone, olanzapine, risperidone, quetiapine. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

CAPRELSA

Products Affected

CAPRELSA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CARGLUMIC ACID

Products Affected

· carglumic acid oral tablet soluble

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CAYSTON

Products Affected

· CAYSTON

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

CHOLBAM

Products Affected

CHOLBAM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For continuation, must provide documentation showing the patient has met 2 of the following laboratory criteria or 1 laboratory criterion plus a body weight increase by 10% (or stability at greater than the 50th percentile): (1) AST or ALT less than 50 U/L (or baseline levels reduced by 80%) (2) total bilirubin less than 1 mg/dL, and (3) no evidence of cholestasis on liver biopsy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

clobazam

Products Affected

- clobazam oral suspension
- clobazam oral tablet

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must first try one generic anticonvulsant. Clobazam suspension may only be used in patients where tablets are contraindicated (e.g., dysphagia). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

clomiphene citrate

Products Affected

• clomiphene citrate oral

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

COMETRIQ

KIT 3 X 20 MG & 80 MG

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL
 COMETRIQ (60 MG DAILY DOSE) KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

COPIKTRA

Products Affected

COPIKTRA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CORTROPHIN

Products Affected

CORTROPHIN

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial-in accordance with FDA label or max of 3 mos. if unspecified in label. Continuation-1 year. |
| Other Criteria | Not covered for FDA-approved indications of acute gouty arthritis, severe psoriasis, and atopic dermatitis. For all covered FDA-approved indications except infantile spasms, must have a therapeutic trial of parenteral glucocorticoid. Supporting documentation for all drug trials is required demonstrating inadequate response, intolerance, or FDA labeled contraindication to therapy. For acute exacerbations of multiple sclerosis: one month trial of oral glucocorticoid. For nephrotic syndrome associated with lupus erythematosus, systemic lupus erythematosus, and inflammatory ocular disorders: one month trial of an immunosuppressant (e.g. cyclophosphamide, tacrolimus, mycophenolate mofetil, methotrexate, azathioprine). For adjunctive therapy for short-term administration rheumatic disease: 12-week trial of one biologic drug. For systemic dermatomyositis (polymyositis): one 12-week trial with rituximab. Continuation of previously authorized therapy requires demonstrated clinical benefit. Quantity limited to dosage as supported by the FDA-approved label. Trial of a Part B drug prior to a Part D drug applies only to beneficiaries enrolled in an MA-PD plan. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |

COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)COSENTYX SENSOREADY (300 MG)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Cosentyx must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For ERA: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one other systemic agent for the condition (e.g., NSAIDs, methotrexate). For all other medically-accepted indications: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator for the condition (e.g. methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

COSENTYX 75MG/0.5ML

Products Affected

 COSENTYX SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 75 MG/0.5ML

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Cosentyx must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ERA: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one other systemic agent for the condition (e.g., NSAIDs, methotrexate). For psoriatic arthritis: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

COTELLIC

Products Affected

COTELLIC

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CRINONE

Products Affected

• CRINONE VAGINAL GEL 8 %

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

CYSTADROPS

Products Affected

CYSTADROPS

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

CYSTARAN

Products Affected

CYSTARAN

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

DALFAMPRIDINE ER

Products Affected

• dalfampridine er

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Patient must not have history of seizure and creatinine clearance must be greater than 50 ml per min. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval for 12 weeks, recertification required every 12 months therafter |
| Other Criteria | Baseline timed 25-foot walk (T25FW), patient must be currently ambulatory. Continuation stability and/or improvement in walking speed. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

DALIRESP

Products Affected

DALIRESP

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have an FEV1 less than 50%. Patient must have had more than one COPD exacerbation in the past year. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have tried and failed triple therapy with an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting antimuscarinic (LAMA) in the past 6 months (failure is defined as no improvement, a worsening of the condition, or an intolerance after trying triple therapy at the maximum dosages for at least 4 weeks consistently). For continuation, documentation must be provided showing a reduction in COPD exacerbations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

DAURISMO

Products Affected

• DAURISMO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

DIACOMIT

Products Affected

DIACOMIT

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

diclofenac epolamine patch

Products Affected

diclofenac epolamine external

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

dihydroergotamine spray

Products Affected

• dihydroergotamine mesylate nasal

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must try and fail (defined as inability to improve symptoms or condition) one triptan drug AND Ubrelvy or Reyvow. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

dimethyl fumarate

Products Affected

- dimethyl fumarate oral
- dimethyl fumarate starter pack

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

DOJOLVI

Products Affected

DOJOLVI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must provide documentation supporting the diagnosis (e.g., medical records). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 months |
| Other Criteria | Patient must not have pancreatic insufficiency. For continuation, patient must have clinically significant benefit compared to baseline (e.g., reduced hospitalizations, myopathy, cardiac symptoms, muscle weakness, etc.). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

droxidopa

Products Affected

droxidopa

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval: 3 months. Continuation: 1 year. |
| Other Criteria | Patient must first try midodrine. For continuation: Must have documentation of a positive clinical response (e.g., sustained decrease in dizziness). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

DUPIXENT

Products Affected

DUPIXENT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | For eosinophilic esophagitis: (1) diagnosis confirmed by esophageal biopsy defined by at least 15 eosinophils per high power field (HPF), and (2) patient's current weight is at least 40 kg. For prurigo nodularis: Must have moderate to severe prurigo nodularis defined as a score of at least 7 on the Worst Itching Intensity Numerical Rating Scale (WI-NRS) and at least 20 nodular lesions. |
| Age Restrictions | |
| Prescriber Restrictions | For prurigo nodularis, must be prescribed by a dermatologist. |
| Coverage Duration | Authorized for 1 year. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------|---|
| Other Criteria | For atopic dermatitis in patients 2 years of age and older: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one medium or higher potency topical steroid (e.g., clobetasol) - AND - one topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus). For atopic dermatitis in patients younger than 2 years of age: Must have a documented trial and failure (defined above) to one medium or higher potency topical steroid (e.g., clobetasol). For asthma: Must have a documented trial and failure with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (failure is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). For chronic rhinosinusitis with nasal polyp: Must have a documented trial and failure (defined as an inability to improve symptoms for least 12 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid. For eosinophilic esophagitis: (1) Patient must have symptoms of esophageal dysfunction - AND - (2) patient must have a documented trial and failure (defined as an intolerance or inability to achieve and maintain remission of low or mild disease activity) with one proton pump inhibitor for at least 2 months - AND - (3) must have a documented trial and failure (defined above) to one topical steroid (e.g., fluticasone, budesonide) for at least 2 months. For prurigo nodularis: Must have a documented trial and failure (defined as inability to improve the condition) to the following: one oral antihistamine and either a medium or higher potency topical steroid or a topical calcineurin inhibitor. For continuation of previously approved indications: Must have documentation demonstrating clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

EMGALITY

Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with Botox (botulinum toxin) or other CGRP antagonist therapy. |
| Required Medical Information | Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a neurologist, pain specialist, or other headache specialist. |
| Coverage Duration | One year initial and continuation. All dosing must align with FDA-approved labeling. |
| Other Criteria | For migraine prevention: Must have a documented trial and failure to two of the following drugs, each from a different group (a, b, c): (a) topiramate, divalproex, valproic acid, (b) propranolol, metoprolol, and (c) amitriptyline or venlafaxine (drugs must be tried for at least 28 days each, with failure defined as an intolerance or an inability to improve the condition). For episodic cluster headache: Must have a documented trial and failure (defined as an intolerance or an inability to improve the condition) to verapamil, corticosteroids, or lithium. For continuation of all previously approved conditions: Must provide evidence of clinical improvement (e.g., decrease in migraine days per month). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ENBREL

Products Affected

- ENBREL SUBCUTANEOUS SOLUTION 25 MG/0.5ML
- ENBREL SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 25 MG/0.5ML, 50
- MG/ML
- ENBREL SUBCUTANEOUS SOLUTION RECONSTITUTED
- ENBREL SURECLICK SUBCUTANEOUS

SOLUTION AUTO-INJECTOR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Enbrel must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For psoriatic arthritis or rheumatoid arthritis: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). For hidradenitis suppurativa: Must have a documented trial and failure (defined above) with an antibiotic therapy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ENBREL MINI

Products Affected

ENBREL MINI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Enbrel must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For psoriatic arthritis or rheumatoid arthritis: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). For hidradenitis suppurativa: Must have a documented trial and failure (defined above) with an antibiotic therapy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ENSPRYNG

Products Affected

• ENSPRYNG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For NMOSD, must provide documentation of anti-aquaporin-4 (AQP4) antibody positive status in chart notes or medical records. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist. |
| Coverage Duration | One year - 3 syringes in month one, 1 syringe per month thereafter |
| Other Criteria | Patient must have had at least one attack requiring rescue therapy in the last year or two attacks requiring rescue therapy in the last 2 years. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

EPCLUSA

Products Affected

• EPCLUSA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist. |
| Coverage Duration | 12 weeks |
| Other Criteria | Criteria will be applied consistent with current AASLD-IDSA guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

EPIDIOLEX

Products Affected

• EPIDIOLEX

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ERIVEDGE

Products Affected

• ERIVEDGE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ERLEADA

Products Affected

• ERLEADA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

erlotinib

Products Affected

· erlotinib hcl

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ESBRIET

Products Affected

• ESBRIET ORAL CAPSULE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Prescriber must rule out other known causes of interstitial lung disease. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

EVENITY

Products Affected

EVENITY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient's T-score must be provided |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 months total therapy |
| Other Criteria | For diagnosis of postmenopausal osteoporosis, the following criteria must be met: documented therapeutic trial with failure, contraindication, or intolerance (defined as creatinine clearance less than 35 mL/min, inability to remain upright for 30 minutes after dose, esophageal stricture (known stricture or dysphagia), significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to alendronate, risedronate, or ibandronate AND documented therapeutic trial with failure, contraindication, or intolerance (defined as significant decrease in BMD after at least one year of therapy, or new fracture while on therapy) to zoledronic acid (generic Reclast) or Prolia. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

everolimus

- everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg
- everolimus oral tablet soluble

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

EVKEEZA

Products Affected

EVKEEZA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet. |
| Required Medical Information | Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment. Confirmation of HoFH by (1) genetic testing - OR - (2) an untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL with one of the following: cutaneous or tendon xanthoma before age 10 years or elevated untreated LDL-C levels consistent with HeFH in both parents (LDL-C greater than 190 mg/dL). |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist. |
| Coverage Duration | One year |
| Other Criteria | Patient must meet the following: (1) Patient has tried a PCSK9 inhibitor (e.g., Repatha) and LDL-C remains greater than or equal to 70mg/dL - and - (2) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70mg/dL - or - (3) Patient is statin intolerant demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin. For reauthorization, must also have improved and maintained an improved LDL compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

EVRYSDI

Products Affected

• EVRYSDI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For spinal muscular atrophy (SMA), documentation of the genetic test confirming the diagnosis must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by a neurologist or in consultation with a neurologist with experience treating SMA. |
| Coverage Duration | Initial - 12 months, continuation - 12 months |
| Other Criteria | Patient must not be receiving concurrent Spinraza or have previously received or be planning to receive gene therapy for SMA (Zolgensma). For continuation, must provide documentation showing a clinically significant improvement in SMA symptoms (e.g., progression, stabilization, decreased decline in motor function) compared to the predicted and natural trajectory of the disease. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

EXKIVITY

Products Affected

EXKIVITY

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

FARYDAK

Products Affected

FARYDAK

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 48 weeks |
| Other Criteria | Limited to 6 capsules for every 21-day cycle. Covered for 16 cycles when approved. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

FASENRA

- FASENRA
- FASENRA PEN

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/µL at therapy start, OR greater than or equal to 300 cells/µL in the previous 12 months. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and continuation. All dosing must align with FDA-approved labeling. |
| Other Criteria | Must have a documented trial and failure with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (failure is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks). For continuation of previously approved requests: Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

fentanyl citrate transmucosal

Products Affected

• fentanyl citrate buccal lozenge on a handle

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | Patient must be age 16 or over |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must first try two short-acting oral opioids (e.g., oxycodone, morphine sulfate, hydromorphone). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

FINGOLIMOD

Products Affected

fingolimod hcl

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

FINTEPLA

Products Affected

FINTEPLA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

Firdapse

Products Affected

FIRDAPSE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have clinical symptoms of LEMS (i.e., proximal extremity weakness) that interfere with daily activities. Must provide a baseline disease severity score using the Quantitative Myasthenia Gravis (QMG) or the Triple-Timed Up-And-Go (3TUG) test. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval for 4 weeks. Subsequent approvals will be for 12 months. |
| Other Criteria | The following criteria must be met for initial coverage: (1) If the patient has cancer associated with LEMS, cancer must have been appropriately treated - AND - (2) patient must not have history of seizures, or an increased risk of seizures due to a condition (e.g., brain metastases) and/or medication (e.g., bupropion) - AND - (3) patient must be ambulatory - AND - (4) - for adults only, patient must have documented trial and failure (defined as an intolerance or inability to improve symptoms) to pyridostigmine. For continuation of previously approved requests: Must have documentation showing improvement or stabilization in condition using the QMG or 3TUG test. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

FOTIVDA

Products Affected

FOTIVDA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For advanced renal cell carcinoma, must have clear-cell histology. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GALAFOLD

Products Affected

GALAFOLD

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have a confirmed diagnosis of Fabry disease and documentation of an amenable galactosidase alpha gene variant based on in vitro assay data. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 months |
| Other Criteria | Patient must not be taking Galafold in combination with enzyme replacement therapy (ERT), such as Fabrazyme. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GATTEX

Products Affected

GATTEX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval is 6 months. Susbequent approval for one year. |
| Other Criteria | Patient must be dependent on parenteral support for 12 months or greater. Continuation requires documentation of clinical benefit from Gattex (e.g., reduction in parenteral support, sustained response after reduction, etc.). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GAVRETO

Products Affected

GAVRETO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GILOTRIF

Products Affected

• GILOTRIF

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GLASSIA

Products Affected

• GLASSIA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry) |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

glatiramer

Products Affected

• glatiramer acetate

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GLATOPA

Products Affected

• GLATOPA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

GROWTH HORMONE

- GENOTROPIN MINIQUICK SUBCUTANEOUS PREFILLED SYRINGE
- GENOTROPIN SUBCUTANEOUS CARTRIDGE
- NORDITROPIN FLEXPRO SUBCUTANEOUS SOLUTION PEN-INJECTOR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | |
| Required Medical Information | FOR CHILDREN: must submit an untreated growth velocity curve with a minimum of 1 year of growth data showing a growth velocity of less that 10th % for bone age and gender, growth plates must be open, bone age must be a minimum of 1 year behind chronological age (unless GHD is related to pituitary surgery, radiation therapy, or with precocious puberty), must have a documented GH deficiency via 2 growth hormone stimulation tests below 10ng/ml or GH stimulation test level less than 15 ng/ml + IGF-1 and IGF-PB3 levels below normal for bone age and sex, decreased muscle tone by exam. FOR ADULTS with a diagnosis of GHD: Must have confirmation of GHD by meeting one of the following: (1) A suboptimal response using an appropriate GH-stimulation test, (2) Childonset GHD with confirmed persistent GHD, or (3) patient has all the following: (a) documented pituitary or hypothalamic disease (e.g., brain tumor with previous brain irradiation), (b)greater than or equal to 3 pituitary hormone deficiencies (thyroid-stimulating hormone (TSH), corticotropin (ACTH), and gonadotropins), and (c) low insulin-like growth factor-1 (IGF-1). If IGF-1 value is indeterminate, a suboptimal response on an appropriate GH-stimulation test required. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by an endocrinologist, gastroenterologist, or nephrologist. |
| Coverage Duration | One year |

| PA Criteria | Criteria Details |
|----------------|--|
| Other Criteria | FOR CHILDREN: Diagnosis of Growth Hormone Deficiency-height must be less than the 5th% fir age/sex. Diagnosis of Turner's syndrome-height must be less than 10th%. Diagnosis of Pre-transplant chronic renal insufficiency-height must be less than 5th% for age/sex and patient must be receiving weekly dialysis or SCR less than 2 mg/dL. FOR CHILDREN: must not have constitutional growth delay, or acute or chronic catabolic illness. FOR ADULTS, the following conditions are not covered: treatment of reduced growth hormone related to aging, Turner's syndrome or cystinosis. For continuation in adults and children: Above normal IGF-1 level requires provider attestation that dose will be decreased and therapy will be managed to obtain a level within normal range. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

HEMADY

Products Affected

HEMADY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must try and fail dexamethasone oral tablet (generic Decadron) for current multiple myeloma treatment. Fail is defined as having an intolerance to an inability to improve the condition. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

HETLIOZ

Products Affected

HETLIOZ

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by a sleep specialist or a neurologist. |
| Coverage Duration | One year |
| Other Criteria | Patient must be totally blind. For continuation: must have documented benefit from use of Hetlioz. Not covered for a diagnosis of Smith-Magenis Syndrome (SMS). |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |

HUMIRA

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS PREFILLED SYRINGE KIT 80 MG/0.8ML, 80 MG/0.8ML & 40MG/0.4ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA PEN-CD/UC/HS STARTER

- HUMIRA PEN-PEDIATRIC UC START
- HUMIRA PEN-PS/UV/ADOL HS START SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.8ML
- HUMIRA PEN-PSOR/UVEIT STARTER
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML

| DA 0 '' ' | |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Humira must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For Crohns disease, psoriatic arthritis, or rheumatoid arthritis: Must have a documented trial and failure (defined above) to one non-biologic immunomodulator (e.g. azathioprine, 6-mercaptopurine, methotrexate). For hidradenitis suppurativa: Must have a documented trial and failure (defined above) with an antibiotic therapy. For uveitis: Must have a documented trial and failure (defined above) to one other agent for the condition (e.g., topical steroid, methotrexate). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

IBRANCE

Products Affected

IBRANCE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

icatibant acetate

- icatibant acetate
- sajazir

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of an angiotensin-converting enzyme (ACE) inhibitor is not covered. |
| Required Medical Information | For HAE Type I or II, documentation of C4, C1-INH protein, and C1-INH function lab results. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE. |
| Coverage Duration | 6 months, initial and continuation. Limited to 3 syringes (9mls) every 30 days. |
| Other Criteria | For continuation: Must have documentation showing use of previously approved syringes AND a favorable clinical response (decrease in the duration of attacks, quick onset of symptom relief, resolution of symptoms, decrease in attack frequency or severity). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ICLUSIG

Products Affected

 ICLUSIG ORAL TABLET 10 MG, 15 MG, 30 MG, 45 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ICOSAPENT ETHYL

Products Affected

icosapent ethyl

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For severe hypertriglyceridemia, laboratory confirmation of a baseline triglyceride level of at least 500 mg/dL prior to starting icosapent ethyl. For reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and unstable angina requiring hospitalization, laboratory confirmation of a baseline triglyceride level of at least 150mg/dL prior to starting icosapent ethyl. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For cardiovascular (CV) risk reduction, must have either established CV disease (e.g., coronary artery disease, heart attack, stroke) OR diabetes mellitus with 2 or more additional risk factors for CV disease (e.g., smoking, hypertension, elevated CRP) - AND - one of the following: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose - OR - (2) ezetimibe trial with documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial. For hypertriglyceridemia: must have tried fenofibrate for at least 12 weeks with an inability to lower triglycerides below 150mg/dL. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

IDHIFA

Products Affected

• IDHIFA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of IDH2 (isocitrate dehydrogenase-2) mutation must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

imatinib mesylate

Products Affected

• imatinib mesylate oral tablet 100 mg, 400 mg

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Authorized for one year. |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

IMBRUVICA

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For GVHD, must fail one systemic corticosteroid and one immunosuppressant (tacrolimus, cyclosporine). Failure is defined as disease progression, inability to taper steroid dose, or failure to improve after one month of therapy and/or treatment-related toxicity. For GVHD, continuation requires no disease progression of chronic GVHD, recurrence of malignancy, or unacceptable toxicity. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

IMIPRAMINE

- imipramine hcl oral
- imipramine pamoate

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

INGREZZA

Products Affected

INGREZZA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with tetrabenazine or Austedo. |
| Required Medical Information | Baseline documentation of Abnormal Involuntary Movement Scale (AIMS) score must be provided. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval is 6 months, continuation for one year. |
| Other Criteria | For diagnosis of tardive dyskinesia (TD), must have moderate or severe TD, indicated by minimum AIMS score of 3 on item 8 (severity of abnormal movements). For continuation, documentation of improvement compared to baseline AIMS score. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

INLYTA

Products Affected

• INLYTA ORAL TABLET 1 MG, 5 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

INQOVI

Products Affected

INQOVI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must first try IV decitabine. Part B before Part D Step Therapy. Applies only to beneficiaries in an MA-PD plan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

INREBIC

Products Affected

INREBIC

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Baseline platelet count of 50 X 109 cells/L or greater |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval 6 months with continuation approval for 12 months |
| Other Criteria | Patient must be resistant, intolerant, or have a contraindication to Jakafi. Patient must not currently have thiamine deficiency. For continuation, patient must have experienced a 35% reduction in spleen volume (approximately a 50% reduction in spleen size on palpation). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

IRESSA

Products Affected

• IRESSA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ISTURISA

Products Affected

 ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have failed pituitary surgery or have a contraindication to pituitary surgery. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by an endocrinologist |
| Coverage Duration | One year |
| Other Criteria | Patient must have tried and failed two of the following: ketoconzaole, Lysodren, cabergoline, and/or Signifor/LAR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

IVIG

- BIVIGAM INTRAVENOUS SOLUTION 5 GM/50ML
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C INJECTION SOLUTION 1 GM/10ML
- PANZYGA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

JAKAFI

Products Affected

JAKAFI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For myeofibrosis and polycythemia vera: Complete blood count (CBC) prior to initiating therapy (platelet count greater than 50 x 10(9)/L) |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year for initial and continuation |
| Other Criteria | For all conditions, physician must follow dosing recommendations per FDA-approved labeling. Criteria will be applied consistent with current NCCN guidance. For continuation of all conditions, must have had improvement in condition with use of Jakafi. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

KALYDECO

- KALYDECO ORAL PACKET
- KALYDECO ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have laboratory confirmation of ivacaftor-responsive mutation in the CFTR gene. |
| Age Restrictions | Patient must be age 4 months or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

KERENDIA

Products Affected

KERENDIA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For initial treatment, eGFR greater than or equal to 25ml/min/1.73m2. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must try and fail (defined as an inability to improve symptoms) or intolerance to a SGLT2i (e.g., Farxiga or Jardiance) AND must be on maximally tolerated ACEI or ARB. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

KESIMPTA

Products Affected

KESIMPTA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

KEVEYIS

Products Affected

KEVEYIS

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

KISQALI

- KISQALI (200 MG DOSE)KISQALI (400 MG DOSE)KISQALI (600 MG DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

KISQALI FEMARA

- KISQALI FEMARA (400 MG DOSE)
- KISQALI FEMARA (600 MG DOSE)
- KISQALI FEMARA(200 MG DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

KORLYM

Products Affected

KORLYM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by an endocrinologist. |
| Coverage Duration | One year |
| Other Criteria | For continuation of previously approved requests: Must provide documentation of improvement in hyperglycemia control with Korlym. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

KOSELUGO

Products Affected

KOSELUGO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

lapatinib

Products Affected

· lapatinib ditosylate

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ledipasvir-sofosbuvir

Products Affected

· ledipasvir-sofosbuvir

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist |
| Coverage Duration | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Other Criteria | Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LENALIDOMIDE

Products Affected

• lenalidomide

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LENVIMA

- LENVIMA (10 MG DAILY DOSE)
- LENVIMA (12 MG DAILY DOSE)
- LENVIMA (14 MG DAILY DOSE)
- LENVIMA (18 MG DAILY DOSE)
- LENVIMA (20 MG DAILY DOSE)
- LENVIMA (24 MG DAILY DOSE)
- LENVIMA (4 MG DAILY DOSE)
- LENVIMA (8 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LEQVIO

Products Affected

• LEQVIO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with a PCSK9 inhibitor (e.g., Repatha), Nexletol, or Nexlizet. |
| Required Medical Information | Must submit most recent LDL-C level. Must submit documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a cardiologist, endocrinologist, or board-certified lipidologist. |
| Coverage Duration | One year. Limited to 3 syringes year one and 1 syringe every 6 months thereafter. |
| Other Criteria | Patient must meet the following: (1) Patient has tried a PCSK9 inhibitor (e.g., Repatha) and LDL-C remains greater than or equal to 70mg/dL - and - (2) Patient has tried one high-intensity statin (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than or equal to 20 mg daily) and LDL-C remains greater than or equal to 70mg/dL - or - (3) Patient is statin intolerant demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR failing to achieve LDL-C goal because of skeletal-muscle related symptoms that have continued despite both lowering the statin strength and attempting a different statin. For reauthorization, must also have improved and maintained an improved LDL compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

LIDOCAINE PATCH

Products Affected

• lidocaine external patch 5 %

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LIVTENCITY

Products Affected

LIVTENCITY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Baseline CMV DNA level confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 8 weeks |
| Other Criteria | Must not be used concomitantly with other CMV antivirals (e.g., ganciclovir, valganciclovir). Dosing must follow FDA-approved labeling. Must have documented trial and failure with ganciclovir or valganciclovir. For continuation, documentation of response (e.g., CMV DNA level) must be provided. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

LONSURF

Products Affected

LONSURF

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LORBRENA

Products Affected

LORBRENA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of ALK-positive mutation must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LUMAKRAS

Products Affected

LUMAKRAS

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

LUMIZYME

Products Affected

LUMIZYME

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of baseline FVC and/or 6MWT values must be provided. Must provide patient's current weight and requested dose. Documentation of diagnosis confirmation by enzyme assay or genetic testing must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with a specialist in inherited metabolic disorders (e.g., genetic and metabolic specialist, neurologist, cardiologist). |
| Coverage Duration | One year. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For continuation requests, must also provide documentation demonstrating improvement or stabilization in condition. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

LUPKYNIS

Products Affected

LUPKYNIS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concomitant use with a biologic drug for the condition (e.g., Benlysta, rituximab) is not covered. |
| Required Medical Information | Confirmed diagnosis of SLE - AND - a kidney biopsy confirming class 3, 4, and/or 5 disease. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a nephrologist or rheumatologist. |
| Coverage Duration | 12 months initial and continuation. |
| Other Criteria | For initial requests, tried and failed (defined as an inability to improve kidney function) Benlysta and a generic calcineurin inhibitor (e.g., tacrolimus or cyclosporine) - AND -be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a corticosteroid). For continuation of previously approved requests, must have laboratory evidence of response to Lupkynis defined as a urinary protein creatinine ratio less than 0.5 mg/mg and improved or stable eGFR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

LYBALVI

Products Affected

LYBALVI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Current opioid use. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have a documented trial and failure on two atypical antipsychotics, one of which must be aripiprazole or ziprasidone. Failure is defined as an inability to improve the condition and/or unacceptable weight gain in a patient at significant risk for weight-related morbidity and mortality (e.g., type 2 diabetes, hypertension, dyslipidemia, cardiovascular disease). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

LYNPARZA

Products Affected

LYNPARZA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MATULANE

Products Affected

MATULANE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MAVENCLAD

- MAVENCLAD (10 TABS)
- MAVENCLAD (4 TABS)
- MAVENCLAD (5 TABS)
- MAVENCLAD (6 TABS)

- MAVENCLAD (7 TABS)
- MAVENCLAD (8 TABS)
- MAVENCLAD (9 TABS)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years total therapy |
| Other Criteria | Patient must first try glatiramer. Patient must not have concurrent use with other MS disease modifying drugs. Patient must not have clinically isolated syndrome (CIS). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MAVYRET

- MAVYRET ORAL PACKET
- MAVYRET ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must have chronic hepatitis C infection. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist. |
| Coverage Duration | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Other Criteria | Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MAYZENT

- MAYZENT ORAL TABLET 0.25 MG, 1 MG, 2 MG
- MAYZENT STARTER PACK

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MEKINIST

Products Affected

• MEKINIST ORAL TABLET 0.5 MG, 2 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MEKTOVI

Products Affected

MEKTOVI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have documentation of BRAF V600 mutation status |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

METHYLTESTOSTERONE

Products Affected

• methyltestosterone oral

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

modafinil

Products Affected

modafinil

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

MYALEPT

Products Affected

MYALEPT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Laboratory confirmed leptin deficiency. Must have one of the following: triglyceride level more than 200mg/dL or diabetes mellitus. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must not have HIV, infectious liver disease, or acquired lipodystrophy with hematologic abnormalities |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

NATPARA

Products Affected

NATPARA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have two consecutive calcium levels less than 8.9 |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

NERLYNX

Products Affected

NERLYNX

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 months total therapy |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

NEXLETOL

Products Affected

NEXLETOL

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid or PCSK9 inhibitors (e.g., Repatha) will not be approved. |
| Required Medical Information | Must submit most recent LDL-C level. |
| Age Restrictions | |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or other physician who focuses on the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | One year |
| Other Criteria | Must have one of the following for initial approval: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose with failure to reach LDL-C goal - OR - (2) ezetimibe trial with documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

NEXLIZET

Products Affected

NEXLIZET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid or PCSK9 inhibitors (e.g., Repatha) will not be approved. |
| Required Medical Information | Must submit most recent LDL-C level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have one of the following for initial approval: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose with failure to reach LDL-C goal - OR - (2) ezetimibe trial with documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

NIVESTYM

Products Affected

 NIVESTYM INJECTION SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

NUBEQA

Products Affected

NUBEQA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

NUCALA

Products Affected

NUCALA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/µL at therapy start, OR greater than or equal to 300 cells/µL in the previous 12 months. For Hypereosinophilic Syndrome (HES), must have blood eosinophil count at least 1,000 cells/mcL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 yr-Limited to 1 syringe: asthma and CRSwNP and 3 syringes (300mg):HES and EGWP per 28 days |
| Other Criteria | For asthma: Must have a documented trial and failure with triple therapy including an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting antimuscarinic (LAMA) in the past 6 months (failure is defined as an intolerance or inability to improve the condition on triple therapy for at least 4 weeks). For eosinophilic granulomatosis with polyangiitis (EGWP): Must have a documented trial and failure (defined as an inability to improve symptoms) with a non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide). For Hypereosinophilic Syndrome (HES): Must have had 2 flares of HES in the past year (e.g., symptoms requiring steroid or increase in steroid) - AND - Must have a documented trial and failure (defined as an inability to improve symptoms) with a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea). For initial approval for chronic rhinosinusitis with nasal polyps: Must have documentation of disease persistence despite at least 8 weeks of treatment with intranasal steroids - AND - Must be used in combination with an intranasal steroid. For continuation of previously approved requests: Must have documentation showing clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). |
| Indications | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|----------------|------------------|
| Off Label Uses | |

NUEDEXTA

Products Affected

NUEDEXTA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by a neurologist |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

NULIBRY

Products Affected

NULIBRY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of MoCD Type A by genetic testing. Documentation of genetic testing results must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with a physician who specializes in the treatment of inherited metabolic disorders. |
| Coverage Duration | 12 months for initial and continuation. |
| Other Criteria | For continuation requests, must also provide documentation demonstrating a beneficial response to therapy compared to pretreatment baseline in one or more of the following: neurological function, gross motor function, and/or developmental milestones. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

NUPLAZID

Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

OCALIVA

Products Affected

OCALIVA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have one of the following: alkaline phosphatase level greater than or equal to 1.67 times the upper limit of normal, or total bilirubin greater than or equal to 1 times the upper limit of normal but less than 2 times the upper limit of normal. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have received 12 months of ursodiol therapy and have had an inadequate response or be intolerant to ursodiol. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ODOMZO

Products Affected

ODOMZO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

OFEV

Products Affected

OFEV

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For idiopathic pulmonary fibrosis (IPF), must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. For systemic sclerosis related Interstitial Lung Disease (SSc-ILD), diagnosis must be confirmed by HRCT. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For IPF, provider must rule out other known causes of interstitial lung disease. For SSc-ILD, fibrotic disease in the lung must be at least 10%, Forced Vital Capacity (FVC) must be at least 40% of predicted normal - and - SSc disease onset (defined by first non-Raynaud symptom) must be within the 7 past years. Must have disease progression (e.g., greater than or equal to 10 percent decline in FVC or DLCO) on trials of mycophenolate mofetil and cyclophosphamide at maximally tolerated doses, or have medical contraindication to treatment. Provider must attest that the patient is being adequately treated for any complications of SSc (e.g.,pulmonary hypertension) and comorbid disease (e.g., chronic obstructive pulmonary disease - COPD). For chronic fibrosing ILDs, must have a progressive phenotype. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ONUREG

Products Affected

ONUREG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

OPSUMIT

Products Affected

OPSUMIT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For diagnosis of pulmonary aterial hypertension, must be in World Health Organization Group category 1. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ORENCIA

Products Affected

 ORENCIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 125 MG/ML, 50 MG/0.4ML, 87.5 MG/0.7ML

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Orencia must not be used in combination with other biological products. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ORENCIA CLICKJECT

Products Affected

· ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Orencia Clickject must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of psoriatic arthritis or rheumatoid arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ORENITRAM

Products Affected

ORENITRAM

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must first try generic Revatio (sildenafil). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ORGOVYX

Products Affected

ORGOVYX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | When approved, a loading dose of 360 mg (32 tablets) is authorized the first month of treatment. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ORKAMBI

Products Affected

- ORKAMBI ORAL PACKET 100-125 MG, 150-188 MG, 75-94 MG
- ORKAMBI ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have laboratory confirmation of homozygous F508del mutation in the cystic fibrosis transmembrane regulator (CFTR) gene |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ORLADEYO

Products Affected

ORLADEYO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must submit documentation of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis. |
| Age Restrictions | Must be age 12 or older. |
| Prescriber Restrictions | Prescriber must be an allergist, immunologist, hematologist, or other specialist experienced in treating HAE. |
| Coverage Duration | Initial approval: 6 months. Continuation approval: 12 months. |
| Other Criteria | Patient must have attacks either affecting upper airways, involving the face, neck, or abdomen, or resulting in debilitation or dysfunction. Patient must not be on an angiotensin-converting enzyme (ACE) inhibitor. Orladeyo must not be used in combination with other prophylactic therapies for HAE (e.g., Takhzyro). For continuation, must provide documentation showing a decrease in the frequency of acute attacks while on Orladeyo. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

OTEZLA

Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For a diagnosis of psoriasis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, cyclosporine, acitretin). For psoriatic arthritis, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to one non-biologic immunomodulator (e.g. methotrexate, leflunomide, sulfasalazine). For oral ulcers associated with Behcet's disease, must have tried one other systemic therapy (e.g., colchicine, thalidomide, interferon alpha, tumor necrosis factor inhibitors). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

OXERVATE

Products Affected

OXERVATE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation confirming diagnosis must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 8 weeks total treatment |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PANRETIN

Products Affected

PANRETIN

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must first try and fail (defined as an intolerance or inability to improve the condition) with imiquimod 5% cream. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PEMAZYRE

Products Affected

PEMAZYRE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year - dose and frequency must align with FDA label |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

penicillamine

Products Affected

• penicillamine oral tablet

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For cystinuria, documentation that treatment with conservative measures (e.g. high fluid intake, sodium and protein restriction, urinary alkalization) were ineffective, not tolerated, or contraindicated. Quantity limited to dosage as supported by the FDA-approved label. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

pentamidine

Products Affected

• pentamidine isethionate inhalation

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | CD4 lymphocyte count. For patients 30 days to 1 year of age, was the patient born to a mother known to be HIV-infected? Is HIV seropostive or infected? For patients 2 years of age ond older, has the patient experienced at least one episode of PCP? |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have therapeutic trial of Co-trimoxazole (trimethoprim/sulfamethoxazole). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PERSERIS

Products Affected

PERSERIS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must be stable on or be able to tolerate an oral risperidone dose of 3 to 4 mg/day. For Perseris 120 mg, the patient must try and fail Rispderal Consta (fail means the drug was tried at an equivalent dose to currently requested Perseris, but the condition did not improve or patient had an intolerance). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PHENOBARBITAL

Products Affected

- phenobarbital oral elixir
- phenobarbital oral tablet

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PIQRAY

Products Affected

- PIQRAY (200 MG DAILY DOSE)
- PIQRAY (250 MG DAILY DOSE)
- PIQRAY (300 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer, documentation of evidence confirming mutations must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PIRFENIDONE

Products Affected

• pirfenidone oral tablet 267 mg, 801 mg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Prescriber must rule out other known causes of interstitial lung disease. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PLEGRIDY

Products Affected

- PLEGRIDY
- PLEGRIDY STARTER PACK

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

POMALYST

Products Affected

POMALYST

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PRETOMANID

Products Affected

PRETOMANID

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 26 weeks |
| Other Criteria | Must be used in combination with linezolid and Sirturo. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

PREVYMIS

Products Affected

PREVYMIS ORAL

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 100 days |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PROLASTIN-C

Products Affected

 PROLASTIN-C INTRAVENOUS SOLUTION RECONSTITUTED

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

PROLIA

Products Affected

 PROLIA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have a documented trial and failure with alendronate, risedronate, or ibandronate - AND - zoledronic acid. Failure is defined as intolerance, decrease in BMD, or new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture). Part B before Part D Step Therapy. Use of zoledronic acid applies only to beneficiaries enrolled in an MA-PD plan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PROMACTA

Products Affected

• PROMACTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Current platelet count |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | For chronic ITP, must first try IVIG or immunoglobulin. For thrombocytopenia from hepatitis C infection, must also use interferonbased therapy. For aplastic anemia, must be used with standard immunosuppressive therapy (antithymocyte globulin and cyclosporine) for first-line treatment or must have had an insufficient response to cyclosporine or cyclosporine modified for second-line or subsequent treatment. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

PYRUKYND

Products Affected

- PYRUKYND
- PYRUKYND TAPER PACK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Not covered for a patient with any of the following: Homozygous for R479H mutation, 2 non-missense variants in PKLR gene, not regularly transfused. |
| Required Medical Information | Genetic testing confirming diagnosis - AND - Current hemoglobin less than or equal to 10mg/dL - AND -at least six red blood cell (RBC) transfusion episodes within the previous year. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a hematologist. |
| Coverage Duration | Initial: 3 months, Continuation: 12 months |
| Other Criteria | For continuation: Must have documentation of a positive clinical response as determined by the prescriber. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |

QELBREE

Products Affected

 QELBREE ORAL CAPSULE EXTENDED RELEASE 24 HOUR 100 MG, 150 MG, 200 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must first try both atomoxetine and clonidine ER. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

QINLOCK

Products Affected

QINLOCK

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RADICAVA ORS

Products Affected

- RADICAVA ORS
- · RADICAVA ORS STARTER KIT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Medical records supporting the request must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 12 months. Limited to 70 mLs the first 28 days and 50 mLs every 28 days thereafter. |
| Other Criteria | Patient must have a diagnosis of "definite" or "probable" amyotrophic lateral sclerosis (ALS) as defined by the revised El Escorial/Arlie House criteria - AND - patient must have disease duration of less than or equal to 2 years (please provide date of diagnosis) - AND - patient must have retained most activities of daily living defined as a score of greater than or equal to 2 points on each of the 12 items of the revised ALS Functional Rating Scale (ALSFRS-R) (i.e., a minimum score of 24) - AND - patient must have normal respiratory function defined as a percent-predicted forced vital capacity (% FVC) greater than or equal to 80%. For continuation of coverage, patient must have a diagnosis of "definite" or "probable" ALS as defined by the revised El Escorial/Arlie House criteria - AND - patient must have clinical benefit from therapy as determined by the provider - AND - patient must not be dependent on invasive ventilation. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RAVICTI

Products Affected

RAVICTI

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RAYALDEE

Products Affected

RAYALDEE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Serum total 25-hydroxyvitamin D level must be less than 30 ng/mL (must be submitted to Priority Health). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have chronic kidney disease (CKD) stage 3 or 4. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REBIF

Products Affected

- REBIF REBIDOSE SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF REBIDOSE TITRATION PACK SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- REBIF SUBCUTANEOUS SOLUTION PREFILLED SYRINGE
- REBIF TITRATION PACK SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RELISTOR

Products Affected

- RELISTOR ORAL
- · RELISTOR SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Patient must not have mechanical gastrointestinal obstruction. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 4 months |
| Other Criteria | Must try and fail (defined as an inadequate response or intolerance) to lactulose and polyethylene glycol (Miralax). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REPATHA

Products Affected

REPATHA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid, Praluent, Nexletol, Nexlizet will not be approved. |
| Required Medical Information | Must submit most recent LDL-C level. For HoFH: Must have a diagnosis of definite HoFH defined by one of the following: (1) genetic testing - OR - (2) an untreated LDL-C greater than 500 mg/dL or a treated LDL-C greater than 300 mg/dL with one of the following: cutaneous or tendon xanthoma before age 10 years OR elevated untreated LDL-C levels consistent with heterzygous FH in both parents (LDL-C greater than 190 mg/dL). |
| Age Restrictions | |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or other physician who focuses on the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | One year |
| Other Criteria | Must have one of the following for initial approval: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose with failure to reach LDL-C goal - OR - (2) Documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial must be provided. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REPATHA PUSHTRONEX SYSTEM

Products Affected

REPATHA PUSHTRONEX SYSTEM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid, Praluent, Nexletol, Nexlizet will not be approved. |
| Required Medical Information | Must submit most recent LDL-C level. For HoFH: Must have a diagnosis of definite HoFH defined by one of the following: (1) genetic testing - OR - (2) an untreated LDL-C greater than 500 mg/dL or a treated LDL-C greater than 300 mg/dL with one of the following: cutaneous or tendon xanthoma before age 10 years OR elevated untreated LDL-C levels consistent with heterzygous FH in both parents (LDL-C greater than 190 mg/dL). |
| Age Restrictions | |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or other physician who focuses on the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | One year |
| Other Criteria | Must have one of the following for initial approval: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose with failure to reach LDL-C goal - OR - (2) Documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial must be provided. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REPATHA SURECLICK

Products Affected

REPATHA SURECLICK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of Juxtapid, Praluent, Nexletol, Nexlizet will not be approved. |
| Required Medical Information | Must submit most recent LDL-C level. For HoFH: Must have a diagnosis of definite HoFH defined by one of the following: (1) genetic testing - OR - (2) an untreated LDL-C greater than 500 mg/dL or a treated LDL-C greater than 300 mg/dL with one of the following: cutaneous or tendon xanthoma before age 10 years OR elevated untreated LDL-C levels consistent with heterzygous FH in both parents (LDL-C greater than 190 mg/dL). |
| Age Restrictions | |
| Prescriber Restrictions | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or other physician who focuses on the treatment of CV risk management and/or lipid disorders. |
| Coverage Duration | One year |
| Other Criteria | Must have one of the following for initial approval: (1) Documented trial with ezetimibe AND one high intensity statin (e.g., atorvastatin or rosuvastatin) or, if a high-intensity statin is not tolerated, one statin at the maximally tolerated dose with failure to reach LDL-C goal - OR - (2) Documented statin intolerance defined as experiencing statin-related muscle symptoms during separate trials of two different statins with symptoms resolving upon discontinuation of the statin during each trial must be provided. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RETEVMO

Products Affected

RETEVMO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REVCOVI

Products Affected

REVCOVI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must provide trough plasma ADA activity and trough dAXP levels. Must provide patient's current weight and requested dose. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year initial and continuation |
| Other Criteria | Provider attestation that treatment will follow FDA-approved labeling with dose adjusted to maintain trough ADA activity over 30 mmol/hr/L, trough dAXP level under 0.02 mmol/L, and/or to maintain adequate immune reconstitution based on clinical assessment of the patient. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

REVLIMID

Products Affected

REVLIMID

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

REYVOW

Products Affected

• REYVOW ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other CGRP antagonist therapy. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Unless contraindicated per the FDA label, trial and failure (defined as intolerance or an inability to improve symptoms) with two different triptan medications. Reyvow will not be covered for migraine prevention. Quantities to treat more than 4 migraines per month are not covered. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

REZUROCK

Products Affected

REZUROCK

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and continuation. |
| Other Criteria | Other criteria will be applied consistent with current NCCN guidance. Reauthorization for GVHD: Must have documentation of clinical benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RINVOQ

Products Affected

 RINVOQ ORAL TABLET EXTENDED RELEASE 24 HOUR 15 MG, 30 MG, 45 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | For NRAS, RA, PsA, AS and UC, prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For RA and PsA: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one non-biologic immunomodulator (e.g. (methotrexate, leflunomide, sulfasalazine, hydroxychloroquine). For ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (NRAS), must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For atopic dermatitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one medium or higher potency topical steroid (e.g., clobetasol) or a topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - AND - one non-biologic immunomodulator drug (e.g., methotrexate or cyclosporine). For continuation of previously approved indications for atopic dermatitis: Must have documentation demonstrating clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ROFLUMILAST

Products Affected

roflumilast

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have an FEV1 less than 50%. Patient must have had more than one COPD exacerbation in the past year. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have tried and failed triple therapy with an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), and a long-acting antimuscarinic (LAMA) in the past 6 months (failure is defined as no improvement, a worsening of the condition, or an intolerance after trying triple therapy at the maximum dosages for at least 4 weeks consistently). For continuation, documentation must be provided showing a reduction in COPD exacerbations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ROZLYTREK

Products Affected

ROZLYTREK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of NTRK gene fusion must be submitted for NTRK gene fusion positive solid tumors. Documentation of ROS 1 mutation testing must be submitted for ROS1 positive non-small cell lung cancer. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RUBRACA

Products Affected

RUBRACA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

RUFINAMIDE

Products Affected

• rufinamide

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

RUZURGI

Products Affected

RUZURGI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must have clinical symptoms of LEMS (i.e., proximal lower extremity weakness) that interfere with daily activities - AND - Must provide baseline disease severity score using the Triple-Timed Up-And-Go (3TUG) test. |
| Age Restrictions | Patient must be between the ages of 6 and 16 years. |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval for 3 months. Subsequent approvals for 12 months. |
| Other Criteria | The following criteria must be met for initial approval: (1) Must not have a history of seizures, or an increased risk of seizures due to a condition (e.g., brain metastases) and/or medication (e.g., bupropion) - AND - (2) Must be ambulatory - AND - (3) If the patient has cancer associated with LEMS, cancer must have been appropriately treated. For continuation of previously approved requests: Must have documentation showing improvement or stabilization in condition using the 3TUG test. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

RYDAPT

Products Affected

RYDAPT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For diagnosis of acute myeloid leukemia (AML), patient must have FLT3 mutation-positive disease as detected by an FDA-approved test. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | One year. For AML, limited to 6 cycles. |
| Other Criteria | For diagnosis of AML, patient must be using Rydapt in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SCEMBLIX

Products Affected

SCEMBLIX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For all indications, Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. For PH+ CML-CP with T315I mutation, documentation confirming mutation must be provided. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with an oncologist. |
| Coverage Duration | 1 year. Limit 60 tabs per 30 days. For CML with T315L mutation, limit to 300 tabs per 30 days. |
| Other Criteria | For PH+ CML-CP with T315I mutation, must submit documentation of a trial & failure (defined as disease progression, inadequate response or intolerance) of Iclusig. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SEROSTIM

Products Affected

 SEROSTIM SUBCUTANEOUS SOLUTION RECONSTITUTED 4 MG, 5 MG, 6 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

SIGNIFOR

Products Affected

SIGNIFOR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must be too ill for pituitary surgery or patient must have had surgery that failed to completely removed the tumor. Patient must have a documented trial with ketoconazole to reduce cortisol secretion. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SIKLOS

Products Affected

SIKLOS

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

SILDENAFIL CITRATE

Products Affected

• sildenafil citrate oral tablet 20 mg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For pulmonary arterial hypertension (PAH), patient must have a PAH classification that meets World Health Organization (WHO) Group 1 criteria. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SIVEXTRO

Products Affected

SIVEXTRO ORAL

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Culture and sensitivity results showing the patient's infection is not susceptible to alternative antibiotic treatments. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be an infectious disease specialist or have consulted with an infectious disease specialist. |
| Coverage Duration | 6 days |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SKYRIZI

Products Affected

- SKYRIZI (150 MG DOSE)
- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Skyrizi must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year. |
| Other Criteria | For psoriasis, psoriatic arthritis, and Crohn's disease: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one non-biologic immunomodulator for the condition (e.g. azathioprine, methotrexate, cyclosporine, acitretin, leflunomide, sulfasalazine). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SORAFENIB

Products Affected

· sorafenib tosylate

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SPRYCEL

Products Affected

• SPRYCEL

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

STELARA

Products Affected

 STELARA SUBCUTANEOUS SOLUTION 45 MG/0.5ML

MG/ML

 STELARA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 45 MG/0.5ML, 90

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Stelara must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For all medically accepted indications, must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to two of the following: Humira, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

STIVARGA

Products Affected

STIVARGA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SUNITINIB MALATE

Products Affected

• sunitinib malate

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

SYMDEKO

Products Affected

• SYMDEKO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have laboratory confirmation of homozygous F508del mutation or have at least one tezacaftor/ivacaftor-responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. |
| Age Restrictions | Must be age 6 or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

SYMPAZAN

Products Affected

SYMPAZAN

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | Must be age 2 years or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must first try and fail generic clobazam. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

SYNRIBO

Products Affected

• SYNRIBO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Authorized for one year. |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TABRECTA

Products Affected

TABRECTA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

tadalafil 2.5mg and 5mg (Cialis)

Products Affected

• tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have tried and failed either 6 months of finasteride or 3 months of dutasteride and must have tried and failed 28 days of alfuzosin, doxazosin, tamsulosin, or terazosin. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

tadalafil 20mg (Adcirca)

Products Affected

tadalafil (pah)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For pulmonary arterial hypertension (PAH), patient must have a PAH classification that meets World Health Organization (WHO) Group 1 criteria. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TAFINLAR

Products Affected

TAFINLAR

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TAGRISSO

Products Affected

TAGRISSO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have laboratory confirmation of epidermal growth factor receptor T790M mutation, or exon 19 deletion or exon 21 (L858R) substitution mutations |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TAKHZYRO

Products Affected

TAKHZYRO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concurrent use of an angiotensin-converting enzyme (ACE) inhibitor - AND - and other preventative therapies for HAE (e.g., Orladeyo, Haegarda) are not covered. |
| Required Medical Information | Patient has attacks either affecting upper airways, involving the face, neck, or abdomen, or resulting in debilitation or dysfunction. Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis. |
| Age Restrictions | Must be age 12 or older. |
| Prescriber Restrictions | Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE. |
| Coverage Duration | Initial approval: 6 months. Continuation approval: 12 months. |
| Other Criteria | For continuation: Must have documentation showing a decrease in the frequency of attacks. After the first 12 months of treatment, must attempt dosing once every 4 weeks if attack free for more than 6 months. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TALZENNA

Products Affected

TALZENNA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TASIGNA

Products Affected

TASIGNA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TAVNEOS

Products Affected

TAVNEOS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of the following to support the diagnosis must be provided: (1) eGFR greater than or equal to 15 mL/min/1.72 m2, (2) at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS) - AND - (3) positive test for either anti-PR3 or anti-MPO. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist and rheumatologist. |
| Coverage Duration | Initial 6 months. Continuation 12 months. |
| Other Criteria | Tavneos must be used as an add-on to standard therapy including cyclophosphamide, rituximab, and steroids (such as methylprednisolone or prednisone) - AND - patient must have a medical need to reduce steroid use if not previously relapsed (ie. infection, osteoporosis) - AND - patient does not currently require dialysis, have kidney transplant, or have received plasma exchange in the past 12 weeks. For continuation: Must have a reduction in the Birmingham Vasculitis Activity Score (BVAS) - AND - steroid dose. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TAZVERIK

Products Affected

TAZVERIK

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TEGSEDI

Products Affected

• TEGSEDI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For hereditary transthyretin-mediated (hATTR) amyloidosis with polyneuropathy, diagnosis confirmed by the following: documented transthyretin (TTR) mutation (e.g., V30M) by genetic testing AND documented amyloid deposits in biopsy tissue. Must provide documentation of one of the following: Baseline polyneuropathy disability (PND) score less than or equal to IIIb or baseline FAP Stage 1 or 2. Patient must have a platelet count of greater than or equal to 100 x 109/L. Patient must have a urine protein to creatinine ratio (UPCR) less than 1,000 mg/g. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | 12 months on initial and continuation requests |
| Other Criteria | Patient must present with clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.). Patient must not be receiving Tegsedi in combination with tafamidis (Vyndaqel, Vyndamax) or Onpattro. For continuation, patient must show clinical benefit from Tegsedi (e.g., improved neuropathy symptoms, slowing of disease progression). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TEPMETKO

Products Affected

TEPMETKO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For NSCLC, must provide documentation of a MET exon 14 skipping alteration. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TERIPARATIDE

Products Affected

TERIPARATIDE (RECOMBINANT)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., Forteo) of more than 2 years in a lifetime is not covered. |
| Required Medical Information | Patient's T-score must be provided - AND - Must have ONE of the following: 1) history of fragility fractures, OR 2) a T-score of less than or equal to -2.5 at any site. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years total therapy (inclusive of all parathyroid hormone analogs) |
| Other Criteria | For postmenopausal osteoporosis: Must have a documented trial and failure with alendronate, risedronate, ibandronate, zoledronic acid, or Prolia - AND - Tymlos. Failure is defined as intolerance, decrease in BMD, or new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

testosterone gel

Products Affected

 testosterone transdermal gel 10 mg/act (2%), 12.5 mg/act (1%), 20.25 mg/1.25gm (1.62%), 20.25 mg/act (1.62%), 25 mg/2.5gm (1%), 40.5 mg/2.5gm (1.62%), 50 mg/5gm (1%)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pretreatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels) with a generic injectable testosterone product. Part B before Part D Step Therapy. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

testosterone solution

Products Affected

· testosterone transdermal solution

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Two pre-treatment morning serum total testosterone levels taken on separate days that are less than 300 ng/dL. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pretreatment clinical signs or symptoms of low testosterone other than erectile dysfunction or decreased libido (e.g., depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis), AND 3) has been screened for prostate cancer according to current guidelines, AND 4) has a documented trial and failure (defined as an intolerance or an inability to improve symptoms or testosterone levels) with a generic injectable testosterone product. Part B before Part D Step Therapy. Trial with injectable testosterone applies only to members who are enrolled in a MAPD plan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

tetrabenazine

Products Affected

• tetrabenazine oral tablet 12.5 mg, 25 mg

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with Austedo. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year. |
| Other Criteria | CYP2D6 genotype must be provided for doses greater than 50mg/day. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TEZSPIRE

Products Affected

TEZSPIRE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | For initial coverage of severe eosinophilic asthma: elevated eosinophil level of greater than or equal to 150 cells/µL at therapy start, OR greater than or equal to 300 cells/µL in the previous 12 months. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | 1 year initial and continuation. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For asthma: Must try and fail with 1 ICS/LABA inhaler drug in combination with 1 other asthma controller medication in the past 6 months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least 4 weeks) - and - for reauthorization, must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

THALOMID

Products Affected

THALOMID

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TIBSOVO

Products Affected

TIBSOVO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have documentation of IDH1 mutation status |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

tolvaptan

Products Affected

tolvaptan

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 30 days |
| Other Criteria | Treatment must be initiated in an inpatient setting. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TRETINOIN CAPSULES

Products Affected

tretinoin oral

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TRIKAFTA

Products Affected

TRIKAFTA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For diagnosis of cystic fibrosis, must provide documentation of a F508del mutation or at least one mutation responsive to Trikafta. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

trimipramine

Products Affected

• trimipramine maleate oral

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TRUDHESA

Products Affected

• TRUDHESA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must try and fail (defined as inability to improve symptoms or condition) one triptan drug AND Ubrelvy or Reyvow. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

TRUSELTIQ

Products Affected

- TRUSELTIQ (100MG DAILY DOSE)
- TRUSELTIQ (125MG DAILY DOSE)
- TRUSELTIQ (50MG DAILY DOSE)
- TRUSELTIQ (75MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TUKYSA

Products Affected

• TUKYSA ORAL TABLET 150 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TURALIO

Products Affected

TURALIO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must provide medical records supporting the patient's diagnosis and confirming functional limitation and not amenable to surgery |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TYMLOS

Products Affected

• TYMLOS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., Forteo) of more than 2 years in a lifetime is not covered. |
| Required Medical Information | Patient's T-score must be provided - AND - Must have ONE of the following: 1) history of fragility fractures, OR 2) a T-score of less than or equal to -2.5 at any site. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years total therapy (inclusive of all parathyroid hormone analogs) |
| Other Criteria | Must have a documented trial and failure with alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD, or new fracture while on therapy OR a contraindication to therapy (e.g., creatinine clearance less than 35 mL/min, inability to sit upright for 30 minutes, esophageal stricture). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

TYVASO DPI

Products Affected

- TYVASO DPI MAINTENANCE KIT
- TYVASO DPI TITRATION KIT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For PH-ILD, confirmation of diagnosis by right heart catheterization, 6-minute walk test, and medical record documentation must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with a specialist for the condition. |
| Coverage Duration | 12 months |
| Other Criteria | For PH-ILD, (1) must have attestation from the provider that ILD has been optimally managed prior to use of Tyvaso, (2) only covered for PH-ILD associated with IPF or CTD, and (3) for continuation of coverage, documentation that patient has had a positive clinical response as determined by the provider and includes improvement in the 6MWD compared to baseline. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

UBRELVY

Products Affected

UBRELVY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other CGRP antagonist therapy. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Unless contraindicated per the FDA label, trial and failure (defined as intolerance or an inability to improve symptoms) with two different triptan medications. Ubrelvy will not be covered for migraine prevention. Quantities to treat more than 8 migraines per month are not covered. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

UPTRAVI

Products Affected

- UPTRAVI INTRAVENOUS
- UPTRAVI ORAL TABLET
- UPTRAVI ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have World Health Organization (WHO) group 1 classification of pulmonary arterial hypertension. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VALCHLOR

Products Affected

VALCHLOR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have tried one of the following: topical corticosteroids, topical chemotherapy such as BiCNU an mechlorethamine), topical retinoids, or topical imiquimod. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VERQUVO

Products Affected

VERQUVO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Ejection fraction less than 45% within the past 12 months. |
| Age Restrictions | Must be at least 18 years old. |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a cardiologist. |
| Coverage Duration | One year |
| Other Criteria | Must have chronic NYHA class 2 - 4 heart failure - AND - have been hospitalized for heart failure in the past 6 months or treated with outpatient IV diuretic therapy for heart failure in the past 3 months - AND - tried and failed (defined as an intolerance or inability to improve symptoms) maximally tolerated doses of the following medications in combination: (a) an ACEI, ARB or Entresto, (b) bisoprolol, carvedilol or metoprolol ER, and (c) spironolactone or other diuretic. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

VERZENIO

Products Affected

VERZENIO

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VIJOICE

Products Affected

VIJOICE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | All the following must be met: (1) Patient has a physician-confirmed and documented diagnosis of PROS including evidence of a mutation in the PIK3CA gene, and (2) Patient has at least one target lesion identified on imaging, and (3) Patient's baseline measurable target lesion volume is documented. |
| Age Restrictions | Must be at least 2 years old. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist, vascular specialist, or geneticist. |
| Coverage Duration | Initial: 6 months, Reauthorization: 1 year. |
| Other Criteria | All the following must be met: (1) Patient's condition is severe or life-threatening and systemic treatment is deemed necessary by the treating physician, and (2) for reauthorization of previously approved requests, documentation of a positive response to therapy as determined by the provider and evidenced by at least a 20% reduction in the total measurable target lesion volume if none of the individual target lesions increased greater than or equal to 20% from baseline, no progression of non-target lesions, and no new lesions. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

VITRAKVI

Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of NTRK gene fusion must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VIZIMPRO

Products Affected

VIZIMPRO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of laboratory report confirming EGFR exon 19 deletion or exon 21 L858R mutation must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VONJO

Products Affected

VONJO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Criteria will be applied consistent with current NCCN guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VOTRIENT

Products Affected

VOTRIENT

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

VOXZOGO

Products Affected

VOXZOGO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient's current weight. Documentation of current annualized growth velocity (AGV). Recent documentation of open epiphyses. Documentation of achondroplasias confirmed by genetic testing. |
| Age Restrictions | Patient is 5 to 17 years of age. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a board-certified geneticist, endocrinologist, neurologist, orthopedic surgeon, or specialist with experience in treating achondroplasia. |
| Coverage Duration | One year |
| Other Criteria | For continuation: Must have documentation of a positive clinical response as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

VYNDAMAX

Products Affected

VYNDAMAX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) must be confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided). Diagnosis by radionuclide imaging requires all of the following to be met (documentation must be provided): Grade 2 or 3 cardiac uptake on radionuclide imaging and either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). Patient must have clinical symptoms or cardiomyopathy and heart failure (e.g., dyspnea, edema, angina). |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | 12 months on initial and continuation requests |
| Other Criteria | Vyndamax will not be approved if the patient has primary (light-chain) amyloidosis or if Vyndamax is being used with Onpattro or Tegsedi. For continuation: must continue to meet initial criteria - and - have had a positive clinical response to Vyndamax compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

VYNDAQEL

Products Affected

VYNDAQEL

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) must be confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided). Diagnosis by radionuclide imaging requires all of the following to be met (documentation must be provided): Grade 2 or 3 cardiac uptake on radionuclide imaging and either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). Patient must have clinical symptoms or cardiomyopathy and heart failure (e.g., dyspnea, edema, angina). |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | 12 months on initial and continuation requests |
| Other Criteria | Vyndaqel will not be approved if the patient has primary (light-chain) amyloidosis or if Vyndaqel is being used with Onpattro or Tegsedi. For continuation: must continue to meet initial criteria - and - have had a positive clinical response to Vyndaqel compared to baseline evidenced by objective (e.g., reduced cardiovascular-related hospitalizations, cardiac function) and subjective measures (e.g., function, quality of life). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

WELIREG

Products Affected

WELIREG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XALKORI

Products Affected

XALKORI

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XATMEP

Products Affected

XATMEP

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

XELJANZ

Products Affected

XELJANZ ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Xeljanz must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For arthritis-related conditions in adults, must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonbiologic immunomodulator (e.g., methotrexate, leflunomide). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XELJANZ SOLUTION

Products Affected

XELJANZ ORAL SOLUTION

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XELJANZ XR

Products Affected

XELJANZ XR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Xeljanz XR must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ankylosing spondylitis: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonsteroidal anti-inflammatory drug (NSAID). For other arthritis-related conditions, must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) to one nonbiologic immunomodulator (e.g., methotrexate, leflunomide). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XERMELO

Products Affected

XERMELO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must be experiencing 4 or more bowel movements per day. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Patient must have been receiving stable dose SSA therapy (either longacting release (LAR), depot, or infusion pump) for at least 3 months. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XGEVA

Products Affected

XGEVA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For all medically-accepted indications (except for Giant Cell Tumor of the bone, and for bone metastases from breast, prostate, and lung cancer), must first try zoledronic acid. Trial with zoledronic acid applies only to members enrolled in an MA-PD (Medicare Advantage Prescription Drug) plan. Part B before Part D Step Therapy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XOLAIR

Products Affected

XOLAIR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | For asthma and nasal polyps: Must provide patient's current weight and baseline IgE level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For asthma: Must have a documented trial and failure with an inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) in the past 6 months (failure is defined as an intolerance or inability to improve the condition on an ICS/LABA regimen for at least 4 weeks) - AND - dose must align with FDA-approved dosing based on IgE and weight. For chronic urticaria: Must have a documented trial and failure (defined as an intolerance or inability to improve symptoms) with at least two H1 antihistamines (e.g., levocetirizine, desloratadine) - OR - one H1 antihistamine and at least 1 of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier. For nasal polyps: Must have a documented trial and failure (defined as an inability to improve symptoms) with daily intranasal steroids - AND - Must be used with an intranasal steroid - AND - dose must align with FDA-approved dosing based on IgE and weight. For continuation of all previously approved requests: Must have documentation showing clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XOSPATA

Products Affected

XOSPATA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of laboratory report confirming FLT3 mutation must be submitted. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XPOVIO

Products Affected

- XPOVIO (100 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 50 MG
- XPOVIO (40 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (40 MG TWICE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (60 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 60 MG
- XPOVIO (60 MG TWICE WEEKLY)
- XPOVIO (80 MG ONCE WEEKLY) ORAL TABLET THERAPY PACK 20 MG, 40 MG
- XPOVIO (80 MG TWICE WEEKLY)

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XTANDI

Products Affected

- XTANDI ORAL CAPSULE
- XTANDI ORAL TABLET 40 MG, 80 MG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

XYREM ORAL

Products Affected

XYREM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Patient must not be receiving sedative hypnotics with Xyrem. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a sleep specialist, neurologist, or pulmonologist. |
| Coverage Duration | One year |
| Other Criteria | For narcolepsy with excessive daytime sleepiness, must first try amphetamine salts, dextroamphetamine or methylphenidate - AND - either modafinil or armodafinil with inadequate response or intolerance. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

XYWAV

Products Affected

XYWAV

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Patient must not be receiving sedative hypnotics with Xywav. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency. |
| Required Medical Information | Confirmation of diagnosis by polysomnography. For a diagnosis of idiopathic hypersomnia, must also exclude other common causes of excessive sleepiness (e.g., insufficient sleep, depression, medications, sleep-related breathing disorders). |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a sleep specialist, neurologist, or pulmonologist. |
| Coverage Duration | One year |
| Other Criteria | Must first try amphetamine salts, dextroamphetamine or methylphenidate with inadequate response or intolerance. For narcolepsy, must also try either modafinil or armodafinil with inadequate response or intolerance. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ZEJULA

Products Affected

• ZEJULA

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZELBORAF

Products Affected

ZELBORAF

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZEMAIRA

Products Affected

ZEMAIRA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have a predicted FEV1 value between 30 and 65% and have serum AAT level less than 11 micromoles per liter (80 milligrams per deciliter if measured by radial immunodiffusion or 50 milligrams per deciliter if measure by nephelometry). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ZEPATIER

Products Affected

ZEPATIER

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a gastroenterologist, hepatologist, or infectious disease specialist. |
| Coverage Duration | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Other Criteria | Must first try Epclusa. Criteria will be applied consistent with current AASLD/IDSA guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZEPOSIA

Products Affected

- ZEPOSIA
- ZEPOSIA 7-DAY STARTER PACK
- · ZEPOSIA STARTER KIT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | For ulcerative colitis: Zeposia must not be used in combination with other biological drugs. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | For ulcerative colitis: Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | One year |
| Other Criteria | For ulcerative colitis: Must first have a documented trial and failure (defined as an inability to improve symptoms) or intolerance to Humira and Xeljanz/Xeljanz XR. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZOLINZA

Products Affected

ZOLINZA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | For diagnosis of primary cutaneous T-cell lymphoma, patient must have prior use of two of the following systemic therapies: a retinoid (bexarotene, all-trans retinoic acid, isotretinoin, acitretin), an interferon (IFN-alpha, IFN-gamma), methotrexate, or extracorporeal photopheresis. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZONISADE

Products Affected

ZONISADE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For doses above 400 mg per day, documentation confirming need for further seizure reduction is required. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | Must have tried generic zonisamide capsules with inability to swallow capsule - AND - must have tried and failed (defined as an inability to improve the condition) one other generic antiseizure medication. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZORBTIVE

Products Affected

ZORBTIVE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Four weeks only |
| Other Criteria | Patient must be receiving TPN in conjunction with Zorbtive. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZTALMY

Products Affected

ZTALMY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must provide confirmation of CDKL5 deficiency based on genetic testing - AND - patient's current weight. |
| Age Restrictions | Must be 2 years of age or older. |
| Prescriber Restrictions | Must be prescribed by a neurologist. |
| Coverage Duration | One year |
| Other Criteria | Documented therapeutic failure of at least 2 previous antiepileptic drugs. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |

ZYDELIG

Products Affected

• ZYDELIG

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

ZYKADIA

Products Affected

· ZYKADIA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

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