



2024 Priority Health Medicare Prior Authorization Criteria

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

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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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ACTEMRA

Products Affected

- ACTEMRA ACTPEN
- ACTEMRA SUBCUTANEOUS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs, Otezla, or Ofev. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For systemic sclerosis- related interstitial lung disease (SSc-ILD) , must also have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Actemra concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. For systemic sclerosis- related interstitial lung disease (SSc-ILD): Lung fibrosis must be at least 10% - and - patient must try and fail (defined as an intolerance or inability to improve the condition) mycophenolate or cyclophosphamide at maximally tolerated doses - and - 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) - and - for reauthorization, must have documentation of improvement in condition. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

| PA Criteria | Criteria Details |
|--------------------------------|------------------|
| Part B Prerequisite | No |

ACTHAR

Products Affected

- ACTHAR
- ACTHAR GEL

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | Acthar Gel is only covered for the treatment of infantile spasms. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 6 weeks |
| Other Criteria | Covered for infantile spasms after trial and failure (defined as an intolerance or inability to improve the condition) with Cortrophin. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ADALIMUMAB-ADAZ

Products Affected

- *adalimumab-adaz*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ADALIMUMAB-FKJP

Products Affected

- *adalimumab-fkjp (2 pen)*
- *adalimumab-fkjp (2 syringe) subcutaneous prefilled syringe kit 20 mg/0.4ml, 40 mg/0.8ml*
- *adalimumab-fkjp subcutaneous auto-injector kit*
- *adalimumab-fkjp subcutaneous prefilled syringe kit 20 mg/0.4ml, 40 mg/0.8ml*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ADEMPAS

Products Affected

- ADEMPAS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For pulmonary arterial hypertension (PAH), confirmed diagnosis of World Health Organization (WHO) Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | For PAH, trial and failure (defined as an inability to improve the condition) with sildenafil or tadalafil. For chronic thromboembolic pulmonary hypertension (CTEPH), must be in WHO Group 4 - and - must be classified as inoperable or as persistent/recurrent after pulmonary endarterectomy. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AIMOVIG

Products Affected

- AIMOVIG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other CGRP antagonist therapy. |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial: 1 year. Reauth: 2 years. Dosing must align with FDA labeling. |
| Other Criteria | For migraine prevention initial requests: Must have at least four migraine days per month - AND - Must try and fail two of the following generic migraine prevention drugs, each from a different class: amitriptyline, nortriptyline, venlafaxine, propranolol, metoprolol, timolol, valproic acid, divalproex, or topiramate (drugs must be tried for at least 28 days each with fail defined as an intolerance or inability to improve the condition) - AND - for migraine prevention reauthorization: Must provide documentation of a decrease in migraine days per month with use of Aimovig. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AJOVY

Products Affected

- AJOVY

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other CGRP antagonist therapy |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial: 1 year. Reauth: 2 years. Dosing must align with FDA labeling. |
| Other Criteria | For migraine prevention initial requests: Must have at least four migraine days per month - AND - Must try and fail two of the following generic migraine prevention drugs, each from a different class: amitriptyline, nortriptyline, venlafaxine, propranolol, metoprolol, timolol, valproic acid, divalproex, or topiramate (drugs must be tried for at least 28 days each with fail defined as an intolerance or inability to improve the condition) - AND - for migraine prevention reauthorization: Must provide documentation of a decrease in migraine days per month with use of Ajovy. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AKEEGA

Products Affected

- AKEEGA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ALECENSA

Products Affected

- ALECENSA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ALUNBRIG

Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ambrisentan

Products Affected

- *ambrisentan*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. 2 years 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 | |
| Part B Prerequisite | No |

ARALAST

Products Affected

- ARALAST NP INTRAVENOUS SOLUTION
RECONSTITUTED 1000 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have an FEV1 less than 80 percent predicted - AND - a 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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ARCALYST

Products Affected

- ARCALYST

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with an infectious disease specialist. |
| Coverage Duration | Initial approval for 6 months. Reauthorization for 12 months. |
| Other Criteria | For initial review, documentation of failure to obtain negative sputum cultures after a minimum of 6 months of a multidrug background regimen therapy for MAC lung disease must be provided. For reauthorization, documentation of a negative sputum culture obtained within the last 30 days must be provided. Criteria will be applied consistent with current ATS/IDSA guidelines. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

armodafinil

Products Affected

- *armodafinil*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AUGTYRO

Products Affected

- AUGTYRO ORAL CAPSULE 160 MG, 40 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

Auryxia

Products Affected

- AURYXIA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | For a diagnosis of hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis, must first try and fail (defined as an intolerance or inability to improve the condition) sevelamer carbonate or calcium acetate. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AUSTEDO

Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG
- AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 18 MG, 24 MG, 30 MG, 36 MG, 42 MG, 48 MG, 6 MG
- AUSTEDO XR PATIENT TITRATION ORAL TABLET EXTENDED RELEASE THERAPY PACK 12 & 18 & 24 & 30 MG, 6 & 12 & 24

MG

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with tetrabenazine or Ingrezza. |
| Required Medical Information | Documentation of prior therapies and responses to treatment must be provided. For tardive dyskinesia (TD), must also have documentation of the patient's Abnormal Involuntary Movement Scale (AIMS) score. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | Initial: 6 months. Reauth: 2 years. |
| Other Criteria | For tardive dyskinesia (TD) initial requests: Must have tried and failed tetrabenazine (defined as an intolerance or inadequate response). For tardive dyskinesia (TD) reauthorization requests: Must provide documentation of improvement in the AIMS score compared to baseline. For chorea associated with Huntington's disease initial requests: Must have tried and failed tetrabenazine (defined as an intolerance or inadequate response). For chorea associated with Huntington's disease reauthorization requests: Must provide documentation of improvement in chorea symptoms compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AUVELITY

Products Affected

- AUVELITY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | Must try and fail (defined as an inability to improve depressive symptoms after at least 4 weeks of treatment) with an SSRI or SNRI and 1 atypical antidepressant (e.g., bupropion, mirtazapine). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pre-treatment 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

AYVAKIT

Products Affected

- AYVAKIT

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BALVERSA

Products Affected

- BALVERSA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 initial requests: 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 initial requests: 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 | 1 year initial. 2 years reauthorization. |
| Other Criteria | For SLE initial requests: Must be taking two of the following drugs together for at least 12 weeks each: a steroid, immunosuppressant, and/or hydroxychloroquine - AND - For SLE reauthorization: Must have evidence of clinical improvement with Benlysta. For lupus nephritis (LN) initial requests: Must be receiving standard therapy for LN (e.g., mycophenolate or azathioprine plus a steroid) - AND - For LN reauthorization: Must have evidence of clinical improvement with Benlysta, including improved or stable eGFR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BESREMI

Products Affected

- BESREMI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | Must trial and fail hydroxyurea (defined as an intolerance and/or persistence or recurrence of disease). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BETASERON

Products Affected

- BETASERON SUBCUTANEOUS KIT

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

bexarotene

Products Affected

- *bexarotene oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BEXAROTENE GEL

Products Affected

- *bexarotene external*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must first try tazarotene. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

bosentan

Products Affected

- *bosentan*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BOSULIF

Products Affected

- BOSULIF ORAL CAPSULE 100 MG, 50 MG
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BRUKINSA

Products Affected

- BRUKINSA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

BYDUREON

Products Affected

- BYDUREON BCISE

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

BYETTA

Products Affected

- BYETTA 10 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR
- BYETTA 5 MCG PEN SUBCUTANEOUS SOLUTION PEN-INJECTOR

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

CABOMETYX

Products Affected

- CABOMETYX

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CALQUENCE

Products Affected

- CALQUENCE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAMZYOS

Products Affected

- CAMZYOS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For initial coverage, must have (1) a diagnosis of symptomatic NYHA class II or III obstructive hypertrophic cardiomyopathy - AND - (2) a LVEF of 55% or more - AND - (3) previous trial and failure (an inability to improve symptoms), contraindication, or intolerance to beta blockers (such as metoprolol) and non-dihydropyridine calcium channel blockers (verapamil or diltiazem) at doses appropriate for obstructive hypertrophic cardiomyopathy. For reauthorization, must have (1) a LVEF of 50% or more - AND - (2) clinically significant improvement of symptoms (such as improvement in NT-proBNP, decreased shortness of breath, or an improvement in patient reported outcomes assessment). |
| Age Restrictions | Patient is at least 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a cardiologist. |
| Coverage Duration | Initial: 1 year. Reauthorization: 2 years. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAPLYTA

Products Affected

- CAPLYTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of prior therapies and responses to treatment must be provided. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | For schizophrenia: 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. For depressive episodes associated with bipolar 1 disorder: Patient must have tried and failed (defined above) one of the following generic products: quetiapine or olanzapine (with fluoxetine) - AND - Patient must have tried and failed (defined above) generic lurasidone. For depressive episodes associated with bipolar 2 disorder: Patient must have tried and failed (defined above) quetiapine. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAPRELSA

Products Affected

- CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CARGLUMIC ACID

Products Affected

- *carglumic acid oral tablet soluble*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CAYSTON

Products Affected

- CAYSTON

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CHOLBAM

Products Affected

- CHOLBAM

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year initial. Two years reauthorization. |
| Other Criteria | For reauthorization, must have clinical benefit from use of the drug as determined by the provider. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

clobazam

Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

clomiphene citrate

Products Affected

- *clomiphene citrate oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COBENFY

Products Affected

- COBENFY
- COBENFY STARTER PACK

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must have documentation supporting a trial and failure (defined as an inadequate response) with two generic atypical antipsychotics used for at least 28 days each. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a specialist for the condition being treated. |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COMETRIQ

Products Affected

- COMETRIQ (100 MG DAILY DOSE) ORAL KIT 80 & 20 MG
- COMETRIQ (140 MG DAILY DOSE) ORAL KIT 3 X 20 MG & 80 MG
- COMETRIQ (60 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COPIKTRA

Products Affected

- COPIKTRA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. Reauth-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. Reauthorization of previously authorized therapy requires demonstrated clinical benefit. Quantity limited to dosage as supported by the FDA-approved label. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

COSENTYX

Products Affected

- COSENTYX (300 MG DOSE)
- COSENTYX SENSOREADY (300 MG)
- COSENTYX SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE 75 MG/0.5ML
- COSENTYX UNOREADY

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For ERA: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - have aggressive disease that necessitates initial biologic therapy. For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

COTELLIC

Products Affected

- COTELLIC

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CRESEMBA

Products Affected

- CRESEMBA ORAL CAPSULE 186 MG
- *cresemba oral capsule 74.5 mg*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | For invasive aspergillosis, must try and fail (defined as an intolerance or inability to improve the condition) voriconazole. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CRINONE

Products Affected

- CRINONE VAGINAL GEL 8 %

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CYSTADROPS

Products Affected

- CYSTADROPS

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

CYSTARAN

Products Affected

- CYSTARAN

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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, reauthorization required every 12 months thereafter |
| Other Criteria | Baseline timed 25-foot walk (T25FW), patient must be currently ambulatory. Reauthorization requires documentation of stability and/or improvement in walking speed. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DASATINIB

Products Affected

- *dasatinib oral tablet 100 mg, 140 mg, 20 mg, 50 mg, 70 mg, 80 mg*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DAURISMO

Products Affected

- DAURISMO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DAYBUE

Products Affected

- DAYBUE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Patient does not have atypical or variant Rett syndrome. |
| Required Medical Information | Must have documentation of the following: (1) Patient's current weight, (2) diagnosis of classic/typical Rett Syndrome (RTT), AND (3) a documented mutation in the MECP2 gene. |
| Age Restrictions | Must be at least 2 years old. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist. |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | Initial: Must provide documentation of current Rett Syndrome Behavior Questionnaire (RSBQ) score -AND- current Clinical Global Impression-Severity score. For reauthorization: Must provide documentation confirming a positive response to therapy based on the patient's baseline RSBQ and CGIS scores. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DIACOMIT

Products Affected

- DIACOMIT

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DICHLORPHENAMIDE

Products Affected

- *dichlorphenamide*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

diclofenac epolamine patch

Products Affected

- *diclofenac epolamine external*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

dihydroergotamine nasal spray

Products Affected

- *dihydroergotamine mesylate nasal*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have documentation to support (1) a trial and failure (defined as inability to improve symptoms or condition) of one non-oral triptan drug (e.g., sumatriptan nasal spray or injection) AND (2) a trial and failure (defined above) of Ubrelvy. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 initial and reauthorization. |
| Other Criteria | Patient must not have pancreatic insufficiency. For reauthorization, 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 | |
| Part B Prerequisite | No |

DRIZALMA

Products Affected

- DRIZALMA SPRINKLE

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must have documentation of a trial and failure (defined as an inability to improve the condition) with two antidepressants, one of which is duloxetine (generic Cymbalta). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

droxidopa

Products Affected

- *droxidopa*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | Patient must first try midodrine. For reauthorization: Must have documentation of a positive clinical response (e.g., sustained decrease in dizziness). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

DUPIXENT

Products Affected

- DUPIXENT SUBCUTANEOUS SOLUTION AUTO-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PEN-INJECTOR 200 MG/1.14ML, 300 MG/2ML
- DUPIXENT SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/0.67ML, 200

MG/1.14ML, 300 MG/2ML

| 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/L at therapy start, OR greater than or equal to 300 cells/L in the previous 12 months. 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 15 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. 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 | Two years initial and reauthorization. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For asthma: Must try and fail with 1 ICS/LABA inhaler drug 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).</p> <p>For chronic rhinosinusitis with nasal polyp: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use).</p> <p>For atopic dermatitis: Must try and fail (defined as an intolerance or inadequate response) to one medium or higher potency topical steroid (e.g., clobetasol) - or - one topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - AND - for reauthorization, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use).</p> <p>For eosinophilic esophagitis: (1) Patient must have symptoms of esophageal dysfunction - AND - (2) must try and fail (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 try and fail (defined above) to one topical steroid (e.g., fluticasone, budesonide) for at least 2 months - AND - (4) for reauthorization, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use).</p> <p>For prurigo nodularis: (1) Must try and fail (defined as inability to improve the condition) to one oral antihistamine - AND - (2) must try and fail (defined above) a medium or higher potency topical steroid - AND - (3) for reauthorization, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use).</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EMGALITY

Products Affected

- EMGALITY
- EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other CGRP antagonist therapy. |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. Patient has been evaluated for and does not have medication overuse headache (MOH). |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 1 year. Cluster reauth: 1 year. Migraine reauth: 2 years. Dosing must align with FDA labeling. |
| Other Criteria | For migraine prevention initial requests: Must have at least four migraine days per month - AND - Must try and fail two of the following generic migraine prevention drugs, each from a different class: amitriptyline, nortriptyline, venlafaxine, propranolol, metoprolol, timolol, valproic acid, divalproex, or topiramate (drugs must be tried for at least 28 days each with fail defined as an intolerance or inability to improve the condition) - AND - for migraine prevention reauthorization: Must provide documentation of a decrease in migraine days per month with use of Emgality. For cluster headache initial requests: Must try and fail verapamil (fail is defined above) - AND - for cluster headache reauthorization: Must provide documentation of a decrease in the frequency or intensity of cluster headaches with Emgality. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENBREL

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENBREL MINI

Products Affected

- ENBREL MINI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Enbrel concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ENDARI

Products Affected

- ENDARI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must try and fail hydroxyurea. Fail is defined as continuing to have pain episodes despite appropriately dosed hydroxyurea or having any intolerance to hydroxyurea. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years - 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 | |
| Part B Prerequisite | No |

ENTADFI

Products Affected

- ENTADFI

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | use of concomitant generic tadalafil |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 26 weeks |
| 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 | |
| Part B Prerequisite | No |

EOHILIA

Products Affected

- EOHILIA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | (1) Diagnosis of EOE confirmed by esophageal biopsy, defined as at least 15 eosinophils per high power field (HPF) - and - (2) Must have continued symptoms of EOE despite trial of a proton pump inhibitor for at least 2 months - and (3) - Trial with one topical generic corticosteroid (i.e., fluticasone, budesonide) for at least 2 months with continued symptoms. |
| Age Restrictions | Must be 11 years of age or older. |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated (gastroenterologist, allergist). |
| Coverage Duration | 1 year authorization with a limit of 12 weeks of treatment. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

EPIDIOLEX

Products Affected

- EPIDIOLEX

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ERIVEDGE

Products Affected

- ERIVEDGE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ERLEADA

Products Affected

- ERLEADA ORAL TABLET 240 MG, 60 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

erlotinib

Products Affected

- *erlotinib hcl oral tablet 100 mg, 150 mg, 25 mg*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

EVENITY

Products Affected

- EVENITY

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Cumulative use of Evenity of more than 12 months is not covered. |
| Required Medical Information | Must provide documentation of prior therapies and responses to treatment - AND - documentation confirming diagnosis such as T-score. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by endocrinologist. |
| Coverage Duration | 12 months total therapy |
| Other Criteria | Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, 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 | |
| Part B Prerequisite | No |

everolimus

Products Affected

- *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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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, reauthorization - 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 reauthorization, 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 | |
| Part B Prerequisite | No |

FABHALTA

Products Affected

- FABHALTA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Fabhalta is not covered in combination with other complement drug therapy including Soliris, Ultomiris, Empaveli. (Fabhalta has not been studied and there is no data to support use in combination with other medications used for PHN.) |
| Required Medical Information | For initial requests: (1) Must have diagnosis confirmed by flow cytometry, - AND - (2) Must have hemolysis-associated symptoms (thrombosis, organ dysfunction, pain). |
| Age Restrictions | Patient is 18 years of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | For reauthorization, must have documentation of improvement in PNH-related symptoms (e.g., fatigue, dyspnea) - AND - sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FASENRA

Products Affected

- FASENRA PEN
- FASENRA SUBCUTANEOUS SOLUTION
 PREFILLED SYRINGE 10 MG/0.5ML, 30
 MG/ML

| 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/ μ L at therapy start, OR greater than or equal to 300 cells/ μ L 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 | Two years initial and reauthorization. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For asthma: Must try and fail with 1 ICS/LABA inhaler drug 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). Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FILSPARI

Products Affected

- *filspari*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For all requests: Medical records supporting the request must be provided, including documentation of a covered diagnosis, prior therapies, and responses to treatment. For IgAN initial requests: Must also provide (1) documentation confirming biopsy-verified primary immunoglobulin A nephropathy (IgAN) - AND - (2) documentation of a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g - AND - (3) documentation of an eGFR greater than or equal to 30 mL/min/1.73 m2. |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | Must be prescribed by or in consultation with a nephrologist. |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | For IgAN initial requests: (1) Patient must try and fail (defined as an intolerance or an inadequate response after a minimum of 3 months) with a maximally tolerated dose of an ACE inhibitor or ARB - AND - (2) Patient must try and fail (defined above) one other drug for the condition (e.g., mycophenolate, steroids, SGLT2 inhibitor, etc.) - AND (3) Patient must not be currently receiving dialysis - AND - (4) Patient has not undergone kidney transplant. For IgAN reauthorization requests: (1) Must have documentation of a reduced proteinuria - AND - no decline in eGFR compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FILSUVEZ

Products Affected

- FILSUVEZ

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with Vyjuvek. |
| Required Medical Information | For epidermolysis bullosa initial requests: (1) Must have a diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) with genetic testing confirming mutation(s), AND (2) Must have presence of open, partial thickness skin wounds, AND (3) Application is limited to open, partial thickness skin wounds only during dressing change. For epidermolysis bullosa reauthorization requests: (1) Must have presence of open, partial thickness skin wounds, AND (2) Application is limited to open, partial thickness skin wounds only during dressing change, AND (3) documentation confirming Filsuvez is providing clinical benefit must be provided (e.g. complete wound closure, decrease in wound size, reduced body surface area affected by wounds, increase in granulation tissue, decrease in pain and/or infection). |
| Age Restrictions | Must be age 6 months or older. |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a dermatologist or another board-certified prescriber with qualifications to treat dystrophic epidermolysis bullosa. |
| Coverage Duration | 3 months initial and 6 months reauthorization |
| Other Criteria | |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINGOLIMOD

Products Affected

- *fingolimod hcl*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FINTEPLA

Products Affected

- FINTEPLA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. Reauthorization: 2 years. |
| 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 reauthorization: Must have documentation showing improvement or stabilization in condition using the QMG or 3TUG test. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FOTIVDA

Products Affected

- FOTIVDA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

FRUZAQLA

Products Affected

- FRUZAQLA ORAL CAPSULE 1 MG, 5 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

GATTEX

Products Affected

- GATTEX

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of dependence on parenteral support for at least 12 months must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Initial approval is 6 months. Reauthorization: 1 year. |
| Other Criteria | For reauthorization: Documentation that the patient has had a sustained decreased in parenteral support from baseline as documented by an actual change in volume must be provided. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GAVRETO

Products Affected

- GAVRETO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GEFITINIB

Products Affected

- *gefitinib*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GILOTRIF

Products Affected

- GILOTRIF

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

glatiramer

Products Affected

- *glatiramer acetate subcutaneous solution
prefilled syringe 20 mg/ml, 40 mg/ml*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GLATOPA

Products Affected

- GLATOPA SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE 20 MG/ML, 40
MG/ML

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

GROWTH HORMONE

Products Affected

- NORDITROPIN FLEXPRO
SUBCUTANEOUS SOLUTION PEN-INJECTOR
- OMNITROPE SUBCUTANEOUS SOLUTION CARTRIDGE
- OMNITROPE SUBCUTANEOUS SOLUTION RECONSTITUTED

| 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 than 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) Child-onset 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 reauthorization 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 | |
| Part B Prerequisite | No |

HADLIMA

Products Affected

- HADLIMA PUSHTOUCH SUBCUTANEOUS SOLUTION AUTO-INJECTOR 40 MG/0.4ML, 40 MG/0.8ML, 40 MG/0.8ML
- HADLIMA SUBCUTANEOUS SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HEMADY

Products Affected

- HEMADY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

HUMIRA

Products Affected

- HUMIRA (2 PEN) SUBCUTANEOUS AUTO-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA (2 PEN) SUBCUTANEOUS PEN-INJECTOR KIT 40 MG/0.4ML, 40 MG/0.8ML, 80 MG/0.8ML
- HUMIRA (2 SYRINGE) SUBCUTANEOUS PREFILLED SYRINGE KIT 10 MG/0.1ML, 20 MG/0.2ML, 40 MG/0.4ML, 40 MG/0.8ML
- HUMIRA PEN SUBCUTANEOUS PEN-INJECTOR KIT
- HUMIRA SUBCUTANEOUS PREFILLED SYRINGE KIT 40 MG/0.8ML
- HUMIRA-CD/UC/HS STARTER
- HUMIRA-PED<40KG CROHNS STARTER
- HUMIRA-PED>=40KG CROHNS STARTER
- HUMIRA-PED>=40KG UC STARTER
- HUMIRA-PS/UV/ADOL HS STARTER
- HUMIRA-PSORIASIS/UEIT STARTER

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For shortened-interval dosing in IBD, documentation of the following: (1) Two of the following: symptoms, imaging showing active disease, fecal calprotectin greater than 120, CRP greater than or equal to 300, and (2) inadequate drug trough levels, and (3) initial response to therapy. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For hidradenitis suppurativa: Must try and fail (defined above) one other drug for the condition (e.g., prednisone, clindamycin, erythromycin). For uveitis: Must try and fail (defined above) one other drug for the condition (e.g., intraocular or systemic steroids, immunomodulator drugs). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting adalimumab concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician.</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

HYFTOR

Products Affected

- HYFTOR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be receiving systemic mTOR inhibitor therapy (e.g., everolimus). |
| Required Medical Information | Medical records supporting the request must be provided. Must have 3 or more facial angiofibromas. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a dermatologist, neurologist, or geneticist. |
| Coverage Duration | Initial coverage: 3 months. Reauthorization: 1 year. |
| Other Criteria | Must not be a candidate for laser therapy or surgery. Reauthorization: Must have evidence of improvement in facial angiofibromas compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IBRANCE

Products Affected

- IBRANCE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

icatibant acetate

Products Affected

- *icatibant acetate subcutaneous solution prefilled syringe*
- SAJAZIR SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Concurrent use of an angiotensin-converting enzyme inhibitor (ACEI) is not covered. |
| Required Medical Information | Documentation of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis. |
| 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 reauthorization. Limited to 3 syringes (9mls) every 15 days. |
| Other Criteria | For reauthorization: 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 FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IMBRUVICA

Products Affected

- IMBRUVICA ORAL CAPSULE
- IMBRUVICA ORAL SUSPENSION
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | 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 | |
| Part B Prerequisite | No |

INGREZZA

Products Affected

- INGREZZA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with tetrabenazine or Austedo. |
| Required Medical Information | Documentation of prior therapies and responses to treatment must be provided. For tardive dyskinesia (TD), must also have documentation of the patient's Abnormal Involuntary Movement Scale (AIMS) score. |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | Initial: 6 months. Reauth: 2 years. |
| Other Criteria | For tardive dyskinesia (TD) initial requests: Must provide documentation of moderate or severe disease indicated by a minimum score of 3 on item 8 (severity of abnormal movements) of the Abnormal Involuntary Movement Scale (AIMS) - AND - must have tried and failed tetrabenazine (defined as an intolerance or inadequate response). For tardive dyskinesia (TD) reauthorization requests: Must provide documentation of improvement in the AIMS score compared to baseline. For chorea associated with Huntington's disease initial requests: Must have tried and failed tetrabenazine (defined as an intolerance or inadequate response). For chorea associated with Huntington's disease reauthorization requests: Must provide documentation of improvement in chorea symptoms compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INLYTA

Products Affected

- INLYTA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

INQOVI

Products Affected

- INQOVI

| PA Criteria | Criteria Details |
|------------------------------|---------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Patient must first try IV decitabine. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

INREBIC

Products Affected

- INREBIC

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must have tried and failed (defined as an intolerance or inability to improve the condition) Jakafi. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ISTURISA

Products Affected

- ISTURISA ORAL TABLET 1 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 | Two years |
| Other Criteria | Patient must have tried and failed two of the following: ketoconazole, Lysodren, cabergoline, and/or Signifor/LAR. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IVIG

Products Affected

- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA
- GAMUNEX-C

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Must provide current weight and requested dose. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Dosing must follow FDA-approved labeling or have documentation supporting the dose follows accepted standards of medical practice. Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

IWILFIN

Products Affected

- IWILFIN

| 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 | |
| Part B Prerequisite | No |

JAKAFI

Products Affected

- JAKAFI

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | 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 | |
| Part B Prerequisite | No |

JAYPIRCA

Products Affected

- JAYPIRCA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Use of Jaypirca must follow current NCCN recommendations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

JOENJA

Products Affected

- JOENJA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not use in combination with immunosuppressive medications. |
| Required Medical Information | Documentation of activated phosphoinositide 3-kinase delta syndrome (APDS) with PIK3CD or PIK3R1 mutation confirmed by genetic testing. |
| Age Restrictions | Must be at least 12 years old. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a provider who specializes in the management of APDS. |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | Patient must have nodal and/or extranodal lymphoproliferation, history of repeated oto-sino-pulmonary infections and/or organ dysfunction (e.g. lung, liver) - AND - for reauthorization, must provide documentation confirming a positive response to therapy. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

JYLAMVO

Products Affected

- JYLAMVO

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must have documentation to support a trial and failure (defined as an intolerance or inability to improve the condition) with generic methotrexate. Diagnosis will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KALYDECO

Products Affected

- KALYDECO

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Patient must have laboratory confirmation of ivacaftor-responsive mutation in the CFTR gene. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KERENDIA

Products Affected

- KERENDIA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For initial treatment, eGFR greater than or equal to 25ml/min/1.73m ² . |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

KEVEYIS

Products Affected

- KEVEYIS

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KISQALI

Products Affected

- 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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KISQALI FEMARA

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KOSELUGO

Products Affected

- KOSELUGO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

KRAZATI

Products Affected

- *krazati*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Use of Krazati must follow current NCCN recommendations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

lapatinib

Products Affected

- *lapatinib ditosylate*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LAZCLUZE

Products Affected

- LAZCLUZE ORAL TABLET 240 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 | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

LENALIDOMIDE

Products Affected

- *lenalidomide*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LENVIMA

Products Affected

- 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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years. 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 | |
| Part B Prerequisite | No |

LIBERVANT

Products Affected

- LIBERVANT

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIDOCAINE PATCH

Products Affected

- *lidocaine external patch 5 %*
- LIDOCAN
- LIDOCAN III
- TRIDACAINE
- TRIDACAINE II

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Medically accepted indications for lidocaine 5% patch include relief of pain associated with postherpetic neuralgia (PHN), diabetic neuropathy, and cancer-related neuropathic pain. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LIRAGLUTIDE

Products Affected

- *liraglutide*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must have claim or confirmed trial with Trulicity for at least 28 days. Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 reauthorization, documentation of response (e.g., CMV DNA level) must be provided. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LONSURF

Products Affected

- LONSURF

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LORBRENA

Products Affected

- LORBRENA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUMAKRAS

Products Affected

- LUMAKRAS ORAL TABLET 120 MG, 240 MG, 320 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUMIZYME

Products Affected

- LUMIZYME

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with another ERT (e.g., Nexviazyme, Pombiliti). |
| Required Medical Information | Must provide patient's current weight and requested dose. For initial coverage: 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 for the condition (e.g., genetic and metabolic specialist, neurologist, cardiologist). |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For reauthorization requests, must also provide documentation demonstrating improvement or stabilization in condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LUPRON DEPOT

Products Affected

- LUPRON DEPOT (1-MONTH)
INTRAMUSCULAR KIT 3.75 MG
- LUPRON DEPOT (3-MONTH)
INTRAMUSCULAR KIT 11.25 MG
- LUPRON DEPOT-PED (1-MONTH)
- LUPRON DEPOT-PED (3-MONTH)
- LUPRON DEPOT-PED (6-MONTH)

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LYNPARZA

Products Affected

- LYNPARZA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

LYTGOBI

Products Affected

- LYTGOBI (12 MG DAILY DOSE)
- LYTGOBI (16 MG DAILY DOSE)
- LYTGOBI (20 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MATULANE

Products Affected

- MATULANE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MAVYRET

Products Affected

- 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MEKINIST ORAL SOLUTION

Products Affected

- MEKINIST ORAL SOLUTION
RECONSTITUTED

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

METHYLTESTOSTERONE

Products Affected

- *methyldtestosterone oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MIFEPRISTONE

Products Affected

- *mifepristone oral tablet 300 mg*

| 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 reauthorization of previously approved requests: Must provide documentation of improvement in hyperglycemia control with mifepristone. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

modafinil

Products Affected

- *modafinil oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

MOUNJARO

Products Affected

- MOUNJARO

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Patient must not have HIV, infectious liver disease, or acquired lipodystrophy with hematologic abnormalities |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NATPARA

Products Affected

- NATPARA

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Current calcium levels must be provided to confirm dosing follows FDA-approved labeling. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

NEXLETOL

Products Affected

- NEXLETOL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid. |
| 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 | Two years |
| Other Criteria | Patient must meet the following: (1) 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) plus ezetimibe concomitantly for a minimum of 8 weeks and LDL-C remains greater than or equal to 70mg/dL or (2) Patient has tried ezetimibe and 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NEXLIZET

Products Affected

- NEXLIZET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used along with PCSK9 inhibitors (e.g., Repatha), Juxtapid. |
| 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 | Two years |
| Other Criteria | Patient must meet the following: (1) 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) plus ezetimibe concomitantly for a minimum of 8 weeks and LDL-C remains greater than or equal to 70mg/dL or (2) Patient has tried ezetimibe and 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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

nitisinone

Products Affected

- *nitisinone*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NIVESTYM

Products Affected

- NIVESTYM INJECTION SOLUTION
PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NUBEQA

Products Affected

- NUBEQA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NUCALA

Products Affected

- NUCALA SUBCUTANEOUS SOLUTION AUTO-INJECTOR
- NUCALA SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 100 MG/ML, 40
- MG/0.4ML
- NUCALA SUBCUTANEOUS SOLUTION RECONSTITUTED

| 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/ μ L at therapy start, OR greater than or equal to 300 cells/ μ L in the previous 12 months. For Hypereosinophilic Syndrome (HES), must have blood eosinophil count at least 1,000 cells/mcL. 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 | Two years initial and reauthorization. Dosing must follow the FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| 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). For chronic rhinosinusitis with nasal polyp: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For eosinophilic granulomatosis with polyangiitis (EGWP): Must try and fail (defined as an intolerance or inability to improve symptoms) with one traditional, non-biologic immunomodulator (e.g., azathioprine, cyclophosphamide) -- and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For Hypereosinophilic Syndrome (HES): Must have had at least 2 HES flares in the past year defined as symptoms requiring a steroid or increase in current steroid - and - must try and fail (defined as an inability to improve symptoms) with a generic steroid-sparing drug (e.g., methotrexate, hydroxyurea) - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

NUEDEXTA

Products Affected

- NUEDEXTA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Medical records supporting the request, including documentation of the diagnosis, must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by a neurologist. |
| Coverage Duration | Two years |
| Other Criteria | Coverage requires a diagnosis of pseudobulbar affect caused by an underlying neurological condition (ex. amyotrophic lateral sclerosis, multiple sclerosis, stroke). For reauthorization, documentation that Nuedexta caused a decrease in the number of episodes of laughing or crying compared to baseline must be provided. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Initial 1 year. Reauthorization 2 years |
| Other Criteria | For reauthorization 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

ODOMZO

Products Affected

- ODOMZO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OFEV

Products Affected

- OFEV

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For all indications, must have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is or has consulted with a pulmonologist. |
| Coverage Duration | One year initial. Two years reauth. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For idiopathic pulmonary fibrosis (IPF): Prescriber must rule out other known causes of interstitial lung disease - and - must have presence of a UIP pattern on HRCT in patients not subjected to surgical lung biopsy. For chronic fibrosing interstitial lung disease with progressive phenotype: Lung fibrosis must be at least 10% - and - Forced Vital Capacity (FVC) decline must be at least 10% - OR - at least 5% with one of the following: worsening respiratory symptoms OR worsening fibrosis on imaging. For systemic sclerosis- related interstitial lung disease (SSc-ILD): Lung fibrosis must be at least 10% - and - patient must try and fail (defined as an intolerance or inability to improve the condition) mycophenolate or cyclophosphamide at maximally tolerated doses - and - 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). For reauthorization of all indications: must have documentation of improvement in condition. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OGSIVEO

Products Affected

- OGSIVEO ORAL TABLET 100 MG, 150 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OJEMDA

Products Affected

- OJEMDA ORAL SUSPENSION RECONSTITUTED
- OJEMDA ORAL TABLET 100 MG, 100 MG (16 PACK), 100 MG (24 PACK)

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For oral suspension, coverage requires that patient is unable to swallow the tablet formulation. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year. Limited to 1 box per 28 days, based on requested strength. |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OJJAARA

Products Affected

- *ojjaara*

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Criteria will be applied consistent with current NCCN guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ONUREG

Products Affected

- ONUREG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OPFOLDA

Products Affected

- OPFOLDA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used with Lumizyme or Nexviazyme. |
| Required Medical Information | Medical records supporting the request must be provided and include the following: Patient's current weight - AND - For initial coverage: Confirmation of diagnosis by enzyme assay or genetic testing. |
| Age Restrictions | Patient is at least 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a specialist for the condition (such as genetic and metabolic specialists, neurologist, cardiologist, pediatrician). |
| Coverage Duration | Initial: 1 year. Reauthorization: 2 years. Dose will be approved according to the FDA-approved label |
| Other Criteria | Opfolda must be used in combination with Pombiliti. For reauthorization, must ALSO have a documented response to therapy evidenced by improvement or stabilization in the condition (such as improved or stable muscle strength, motor function, cardiac involvement, FVC, and/or 6MWT). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OPSUMIT

Products Affected

- OPSUMIT

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Trial and failure (defined as an inability to improve the condition) with ambrisentan or bosentan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OPSYNVI

Products Affected

- OPSYNVI

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Trial and failure (defined as an inability to improve the condition) with ambrisentan or bosentan. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Orencia concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORENCIA CLICKJECT

Products Affected

- ORENCIA CLICKJECT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Orencia concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORENITRAM

Products Affected

- ORENITRAM
- ORENITRAM MONTH 1
- ORENITRAM MONTH 2
- ORENITRAM MONTH 3

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORGOVYX

Products Affected

- ORGOVYX

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORKAMBI

Products Affected

- ORKAMBI ORAL PACKET
- 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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORLADEYO

Products Affected

- ORLADEYO

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used along with an angiotensin-converting enzyme inhibitor (ACEI) . Must not be used along with other preventative therapies for HAE (e.g., Takhzyro, Haegarda). |
| Required Medical Information | 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 | Two years |
| Other Criteria | For reauthorization: Must also have documentation showing a decrease in the frequency of attacks. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ORSERDU

Products Affected

- ORSERDU ORAL TABLET 345 MG, 86 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Use of Orserdu must follow current NCCN recommendations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OTEZLA

Products Affected

- OTEZLA ORAL TABLET
- OTEZLA ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with biological drugs (e.g., adalimumab). |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For PsO: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g. methotrexate, cyclosporine, acitretin). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For oral ulcers associated with Behcet's disease: Must try and fail (defined above) one other systemic therapy (e.g., colchicine, thalidomide, interferon alpha, tumor necrosis factor inhibitors) for the condition. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OXERVATE

Products Affected

- OXERVATE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | More than 8-weeks of treatment per lifetime will not be covered. |
| Required Medical Information | Documentation confirming diagnosis of Stage 2 (persistent epithelial defect) or stage 3 (corneal ulcer) neurotrophic keratitis such as through slit lamp examination. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, an ophthalmologist. |
| Coverage Duration | 8 weeks total treatment. Dosing must follow the FDA-approved labeling. |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

OZEMPIC

Products Affected

- OZEMPIC (0.25 OR 0.5 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 2 MG/3ML
- OZEMPIC (1 MG/DOSE) SUBCUTANEOUS SOLUTION PEN-INJECTOR 4 MG/3ML
- OZEMPIC (2 MG/DOSE)

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

PANRETIN

Products Affected

- PANRETIN

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

PAZOPANIB

Products Affected

- *pazopanib hcl*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PEMAZYRE

Products Affected

- PEMAZYRE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

penicillamine

Products Affected

- *penicillamine oral tablet*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

PHENOBARBITAL

Products Affected

- *phenobarbital oral elixir*
- *phenobarbital oral tablet*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PIRFENIDONE

Products Affected

- *pirfenidone oral capsule*
- *pirfenidone oral tablet 267 mg, 801 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For all indications, must have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is or has consulted with a pulmonologist. |
| Coverage Duration | Two years |
| Other Criteria | For idiopathic pulmonary fibrosis (IPF): (1) The patient's diagnosis must be confirmed by a surgical lung biopsy or by the presence of a UIP pattern on a HRCT, and (2) the prescriber must rule out other known causes of interstitial lung disease. For reauthorization requests: Documentation of improvement in condition with use of pirfenidone must be provided. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PLEGRIDY

Products Affected

- PLEGRIDY
- PLEGRIDY STARTER PACK

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

POMALYST

Products Affected

- POMALYST

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

PREVYMIS

Products Affected

- PREVYMIS ORAL

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 200 days |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PROLASTIN-C

Products Affected

- PROLASTIN-C

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have an FEV1 less than 80 percent predicted - AND - a 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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

PROLIA

Products Affected

- PROLIA SUBCUTANEOUS SOLUTION
PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must first try and fail (defined as a decrease in BMD or new fracture while on therapy) an oral bisphosphonate or zoledronic acid. If intolerant or contraindicated to an oral bisphosphonate, zoledronic acid is required. Coverage is also provided if the patient has a creatinine clearance less than 35 mL/min. Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

PROMACTA

Products Affected

- PROMACTA ORAL PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Use of Promacta to normalize platelet counts is not covered. |
| Required Medical Information | Current platelet count must be provided. For ITP, initial requests: Patient has a platelet count less than 30,000/mcL - OR - less than 50,000/mcL with bleeding or one of the following risk factor(s) for bleeding: History of clinically significant bleeding at a higher platelet count, concurrent peptic ulcer disease or liver disease that increase bleeding risk, history of falling, or need for concurrent anticoagulation or anti-platelet therapy |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | 3 months |
| Other Criteria | For thrombocytopenia from hepatitis C infection, initial request: The degree of thrombocytopenia is preventing the initiation of interferon therapy OR limits the ability to maintain optimal interferon based therapy. For thrombocytopenia from hepatitis C infection, reauthorization: current platelet count is less than 400 x 109/L - and - patient is responding to therapy as evidenced by increased platelet counts - and - patient continues to receive interferon based therapy. For aplastic anemia, initial requests: 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. For aplastic anemia, reauthorization: current platelet count is less than 400 x 109/L - and - patient is responding to therapy as evidenced by increased platelet counts. For ITP, initial requests: Must have inadequate response or intolerance to steroids or immunoglobulins - AND - either rituximab or splenectomy. For ITP, reauthorization: current platelet count is less than 400 x 109/L - and - patient is responding to therapy as evidenced by increased platelet counts - and - patient remains at risk for bleeding complications. |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------|
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

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. |
| 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, Reauthorization: 12 months |
| Other Criteria | For reauthorization: Must have documentation of a positive clinical response as determined by the prescriber. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Must first try atomoxetine. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

QINLOCK

Products Affected

- QINLOCK

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RADICAVA ORS

Products Affected

- RADICAVA ORS
- RADICAVA ORS STARTER KIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation confirming all required criteria (e.g., diagnosis, labs, ALSFRS-R score) 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. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

REPATHA

Products Affected

- REPATHA
- REPATHA PUSHTRONEX SYSTEM
- REPATHA SURECLICK

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Must submit most recent LDL-C level. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Patient must meet one of the following: (1) 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) plus ezetimibe concomitantly for a minimum of 8 weeks, and LDL-C remains greater than or equal to 70mg/dL - OR - (2) Patient is statin intolerant as demonstrated by experiencing statin-associated rhabdomyolysis to one statin OR has tried both rosuvastatin and atorvastatin and has experienced skeletal-muscle related symptoms on both agents which also resolved upon discontinuation. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RETEVMO

Products Affected

- RETEVMO ORAL CAPSULE 40 MG, 80 MG
- RETEVMO ORAL TABLET 120 MG, 160 MG, 40 MG, 80 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

REVLIMID

Products Affected

- REVLIMID

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

REZDIFFRA

Products Affected

- REZDIFFRA

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For initial requests, documentation supporting the following is required: (1) A diagnosis of metabolic dysfunction-associated steatohepatitis (MASH) or nonalcoholic steatohepatitis (NASH), AND (2) a fibrosis stage of F2 or F3 confirmed by biopsy or NITs, AND (3) an NAFLD Activity Score (NAS) of at least 4, AND (4) current weight, AND (5) a provider attestation that Rezdiffra will be used in conjunction with diet and exercise as per its FDA labeling. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by, or in consultation, with a gastroenterologist or hepatologist. |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | For reauthorization, documentation of the following is required: (1) fibrosis stage of F2 or F3 confirmed by biopsy or NITs, AND (2) documentation supporting improvement or stabilization in steatohepatitis evidenced by fibrosis score or NAFLD Activity (NAS) score. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

REZLIDHIA

Products Affected

- REZLIDHIA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

RINVOQ

Products Affected

- RINVOQ LQ
- 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 or Otezla. |
| Required Medical Information | 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 | Two years initial and reauthorization. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis and non-radiographic axial spondyloarthritis (NRAS): Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Crohn's disease: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For atopic dermatitis: Must try and fail (defined above) one medium or higher potency topical steroid (e.g., clobetasol) - or - one topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus) - AND - for continuation of therapy, must have documented clinical benefit (e.g. less exacerbations, improved symptoms, less steroid use). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |

| PA Criteria | Criteria Details |
|--------------------------------|------------------|
| Part B Prerequisite | No |

RIVFLOZA

Products Affected

- RIVFLOZA SUBCUTANEOUS SOLUTION
- RIVFLOZA SUBCUTANEOUS SOLUTION
 PREFILLED SYRINGE 128 MG/0.8ML, 160
 MG/ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Coverage will not be provided in the following situations: (1) Patient has a history of kidney or liver transplant, AND (2) Patient will be using in combination with Oxlumo. |
| Required Medical Information | (1) Medical records supporting the request must be provided, AND (2) Must have a diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by genetic testing of the AGXT mutation or by liver enzyme analysis, AND (3) must have preserved kidney function with an estimated glomerular filtrate rate (eGFR) of 30 mL/min/1.73m ² or more, AND (4) for reauthorization requests, must have documented clinical benefit with Rivfloza compared to baseline. |
| Age Restrictions | Must be 9 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a nephrologist or urologist. |
| Coverage Duration | Initial: 1 year. Reauth: 2 years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | Rivfloza vials are only covered for children 9 to 11 years old weighing less than 50 kilograms per the FDA-approved labeling. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 reauthorization, documentation must be provided showing a reduction in COPD exacerbations. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ROZLYTREK

Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG
- ROZLYTREK ORAL PACKET

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RUBRACA

Products Affected

- RUBRACA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RUFINAMIDE

Products Affected

- *rufinamide*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

RYBELSUS

Products Affected

- RYBELSUS

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. |
| 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 | |
| Part B Prerequisite | No |

SCEMBLIX

Products Affected

- SCEMBLIX ORAL TABLET 100 MG, 20 MG, 40 MG

| 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. 20 mg limit to 60 tabs per 30 days. 40 mg limit to 240 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SIGNIFOR

Products Affected

- SIGNIFOR

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

SILDENAFIL CITRATE

Products Affected

- *sildenafil citrate oral tablet 20 mg*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SIVEXTRO

Products Affected

- SIVEXTRO ORAL

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of trial with linezolid or culture and sensitivity results showing the patient's infection is not susceptible to linezolid. |
| 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 | |
| Part B Prerequisite | No |

SKYCLARYS

Products Affected

- SKYCLARYS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of genetically confirmed diagnosis - AND - Baseline modified Friedreich's Ataxia Rating Scale (mFARS) score between 20 to 80. |
| Age Restrictions | Must be age 16 years or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist. |
| Coverage Duration | One year initial and reauthorization |
| Other Criteria | Patient must be ambulatory. For reauthorization, documentation that medication is providing clinical benefit based on the patient's baseline mFARS score. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SKYRIZI

Products Affected

- SKYRIZI PEN
- SKYRIZI SUBCUTANEOUS SOLUTION CARTRIDGE 180 MG/1.2ML, 360 MG/2.4ML
- SKYRIZI SUBCUTANEOUS SOLUTION PREFILLED SYRINGE

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For Crohn's disease: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, methotrexate) or a steroid (e.g., prednisone). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For psoriasis: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, cyclosporine, acitretin). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SODIUM OXYBATE

Products Affected

- SODIUM OXYBATE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Patient must not be receiving sedative hypnotics with sodium oxybate. Patient must not suffer from succinic semialdehyde dehydrogenase deficiency. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. Documentation of MSLT and polysomnography confirming diagnosis of narcolepsy. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber must be a sleep specialist or neurologist. |
| Coverage Duration | Two years |
| Other Criteria | For narcolepsy with excessive daytime sleepiness, must first try and fail (defined as an intolerance or inability to improve the condition) amphetamine salts, dextroamphetamine or methylphenidate - AND - either modafinil or armodafinil. For reauthorization requests, must provide documentation demonstrating a decrease in excessive daytime sleepiness with narcolepsy or a decrease in cataplexy episodes. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SORAFENIB

Products Affected

- *sorafenib tosylate*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SPEVIGO

Products Affected

- SPEVIGO INTRAVENOUS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. No more than 2 infusions are covered. |
| Required Medical Information | Medical records supporting the request must be provided. Diagnosis of generalized pustular psoriasis has been confirmed by the following: (1) skin biopsy, (2) systemic symptoms such as fever and fatigue, and (3) relapsing episodes. |
| Age Restrictions | Must be age 12 or older. |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | 1 infusion. Dosing must follow the FDA-approved labeling. |
| Other Criteria | Must first try and fail (defined as an inability to improve flare) one traditional non-biologic immunomodulator drug - AND - must try and fail (defined above) a generic retinoid (ex: acitretin, isotretinoin). For reauthorization of 1 additional infusion: Must have documentation of persistent symptoms and dose must be given 1 week after initial dose. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SPRYCEL

Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

STELARA

Products Affected

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

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| 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: a preferred adalimumab product, Rinvoq, Skyrizi, Actemra, Cosentyx, Otezla, Xeljanz, Xeljanz XR, Orencia or Enbrel. Please Note: preferred adalimumab products include Humira (NDCs starting with -00074), adalimumab-adaz, adalimumab-fkjp, and Hadlima. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

STIVARGA

Products Affected

- STIVARGA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SUCRAID

Products Affected

- SUCRAID

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

SUNITINIB MALATE

Products Affected

- *sunitinib malate*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Must first try and fail generic clobazam. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TABRECTA

Products Affected

- TABRECTA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

tadalafil 20mg (Adcirca)

Products Affected

- *tadalafil (pah)*

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAFINLAR

Products Affected

- TAFINLAR ORAL CAPSULE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAFINLAR TABLET FOR ORAL SUPENSION

Products Affected

- TAFINLAR ORAL TABLET SOLUBLE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | Must be less than 18 years old. |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAGRISSE

Products Affected

- TAGRISSE

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAKHZYRO

Products Affected

- TAKHZYRO SUBCUTANEOUS SOLUTION
- TAKHZYRO SUBCUTANEOUS SOLUTION
 PREFILLED SYRINGE 150 MG/ML, 300
 MG/2ML

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used along with an angiotensin-converting enzyme inhibitor (ACEI). Must not be used along with other preventative therapies for HAE (e.g., Orladeyo, Haegarda). |
| Required Medical Information | Requires submission of C4, C1-INH protein, and C1-INH function lab results confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is an allergist, immunologist, hematologist, or other specialist experienced in treating HAE. |
| Coverage Duration | Two years |
| Other Criteria | For reauthorization: Must also have documentation showing a decrease in the frequency of attacks - and - if attack free, dosing is limited to 1 syringe every 4 weeks. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TALZENNA

Products Affected

- TALZENNA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TASIGNA

Products Affected

- TASIGNA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TASIMELTEON

Products Affected

- *tasimelteon*

| 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 | Two years |
| Other Criteria | Patient must be totally blind. For reauthorization: must have documented benefit from use of tasimelteon. Not covered for a diagnosis of Smith-Magenis Syndrome (SMS). |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 m ² , (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 specialist for the condition. |
| Coverage Duration | Initial 6 months. Reauthorization 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 reauthorization: Must have a reduction in the Birmingham Vasculitis Activity Score (BVAS) - AND - steroid dose. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TAZVERIK

Products Affected

- TAZVERIK

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEGSEDI

Products Affected

- TEGSEDI

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with TTR stabilizers (e.g., tafamidis) or TTR-lowering agents (e.g., Amvuttra, 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 age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | 1 year initial. 2 years 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 - Must not have had a liver transplant - AND - For reauthorization, must have a positive clinical response to Tegsedi 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 | |
| Part B Prerequisite | No |

TEPMETKO

Products Affected

- TEPMETKO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TERIFLUNOMIDE

Products Affected

- *teriflunomide*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TERIPARATIDE

Products Affected

- TERIPARATIDE SUBCUTANEOUS
SOLUTION PEN-INJECTOR 620 MCG/2.
48ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Cumulative use of teriparatide and other parathyroid hormone analogs (e.g., Tymlos) of more than 2 years is not covered. |
| Required Medical Information | Must provide documentation of prior therapies and responses to treatment - AND - documentation confirming diagnosis such as T-score. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by endocrinologist. |
| Coverage Duration | Two years total therapy (inclusive of all parathyroid hormone analogs). |
| Other Criteria | Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, 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 | |
| Part B Prerequisite | No |

testosterone gel

Products Affected

- *testosterone transdermal gel 1.62 %, 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 | Two years |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pre-treatment 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. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

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 | Two years |
| Other Criteria | Approved if the following are met: 1) Patient is male AND 2) has pre-treatment 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. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

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 or Ingrezza. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | CYP2D6 genotype must be provided for doses greater than 50mg/day. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TEZSPIRE

Products Affected

- TEZSPIRE

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | 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 | Two years initial and reauthorization. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For asthma: Must try and fail with 1 ICS/LABA inhaler drug 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). Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

THALOMID

Products Affected

- THALOMID

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TIOPRONIN

Products Affected

- *tiopronin oral tablet*
- *tiopronin oral tablet delayed release 100 mg, 300 mg*

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | For approval: (1) Patient weighs at least 20 kg, (2) Patient has a diagnosis of severe homozygous cystinuria that has not responded to the conservative measures of high fluid intake, alkalinizing therapy, and diet modification including salt and protein restriction alone - and - (3) Patient will be using tiopronin in combination with the above conservative measures. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

TRETINOIN CAPSULES

Products Affected

- *tretinoin oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRIKAFTA

Products Affected

- TRIKAFTA ORAL TABLET THERAPY PACK
- *trikafta oral therapy pack*

| 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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

trimipramine

Products Affected

- *trimipramine maleate oral*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRULICITY

Products Affected

- TRULICITY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

TRUQAP

Products Affected

- TRUQAP ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | For PIK3CA mutations, must first try Piqray. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TURALIO

Products Affected

- TURALIO ORAL CAPSULE 125 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TYENNE

Products Affected

- TYENNE SUBCUTANEOUS

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs, Otezla, or Ofev. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For systemic sclerosis- related interstitial lung disease (SSc-ILD) , must also have documentation of High Resolution Computed Tomography (HRCT) confirming diagnosis. |
| Age Restrictions | |
| Prescriber Restrictions | Prescriber is a specialist or has consulted with a specialist for the condition being treated. |
| Coverage Duration | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Tyenne concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. For systemic sclerosis- related interstitial lung disease (SSc-ILD): Patient must try and fail (defined as an intolerance or inability to improve the condition) mycophenolate or cyclophosphamide at maximally tolerated doses - and - 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) - and - for reauthorization, must have documentation of improvement in condition. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TYMLOS

Products Affected

- TYMLOS

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Cumulative use of Tymlos and other parathyroid hormone analogs (e.g., teriparatide) of more than 2 years is not covered. |
| Required Medical Information | Must provide documentation of prior therapies and responses to treatment - AND - documentation confirming diagnosis such as T-score. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by endocrinologist. |
| Coverage Duration | Two years total (inclusive of all parathyroid hormone analogs) |
| Other Criteria | Must try and fail alendronate, risedronate, or ibandronate - AND - either zoledronic acid or Prolia. Failure is defined as intolerance, decrease in BMD in comparison to previous DEXA scan, 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 | |
| Part B Prerequisite | No |

TYVASO

Products Affected

- TYVASO
- TYVASO REFILL KIT
- TYVASO STARTER KIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For PAH (WHO Group 1): Confirmation of diagnosis by right heart catheterization and medical record documentation must be provided - AND - documentation of prior therapies and responses to treatment must be provided. For PH-ILD (WHO Group 3): 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 | Two years |
| Other Criteria | For PAH, trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND and endothelin receptor antagonist (e.g., ambrisentan or bosentan). 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 6MWT compared to baseline. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

TYVASO DPI

Products Affected

- TYVASO DPI MAINTENANCE KIT
- TYVASO DPI TITRATION KIT

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Coverage for PAH (WHO Group 1) requires confirmation of diagnosis by right heart catheterization and medical record documentation - AND - documentation of any prior therapies and responses to treatment. Coverage of PH-ILD (WHO Group 3) requires confirmation of diagnosis by right heart catheterization, 6-minute walk test, and medical record documentation - AND - documentation of any prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | Must be prescribed by or in consultation with a specialist for the condition. |
| Coverage Duration | Two years |
| Other Criteria | Coverage for PAH (WHO Group 1) requires a trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND and an endothelin receptor antagonist (e.g., ambrisentan or bosentan). Coverage for PH-ILD (WHO Group 3) requires (1) the PH-ILD to be associated with IPF, CTD, or combined IPF and emphysema (CPFE) - AND - (2) for reauthorization, documentation that the patient has had a positive clinical response to Tyvaso as determined by the provider and includes improvement in the 6MWT compared to baseline. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

UPTRAVI

Products Affected

- UPTRAVI
- UPTRAVI TITRATION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan). |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VALCHLOR

Products Affected

- VALCHLOR

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

VANFLYTA

Products Affected

- VANFLYTA

| 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 | |
| Part B Prerequisite | No |

VENCLEXTA

Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VENTAVIS

Products Affected

- VENTAVIS INHALATION SOLUTION 10 MCG/ML, 20 MCG/ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1 by right heart catheterization and medical record documentation. Documentation of prior therapies and responses to treatment. |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Trial and failure (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan). Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VERQUVO

Products Affected

- VERQUVO

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Documentation of prior therapies and responses to treatment must be provided. Documentation of an ejection fraction less than 45% assessed within the past 12 months must be provided. |
| Age Restrictions | Must be at least 18 years old. |
| Prescriber Restrictions | Must be prescribed by, or in consultation with, a cardiologist. |
| Coverage Duration | Two years |
| Other Criteria | Patient has symptomatic worsening chronic heart failure (NYHA class 2 to 4) - AND - has 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 - has tried and failed (defined as an intolerance or inability to improve symptoms) maximally tolerated doses of the following medications in combination: an ACEI, ARB, or ARNi (such as enalapril or Entresto) - AND - bisoprolol, carvedilol or metoprolol ER - AND - spironolactone or other diuretic. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VERZENIO

Products Affected

- VERZENIO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VICTOZA

Products Affected

- VICTOZA SUBCUTANEOUS SOLUTION
PEN-INJECTOR

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must have claim or confirmed trial with Trulicity for at least 28 days. Only covered for the treatment of Type 2 Diabetes Mellitus. |
| Indications | Some FDA-approved Indications Only. |
| Off Label Uses | |
| Part B Prerequisite | No |

VIGAFYDE

Products Affected

- VIGAFYDE

| PA Criteria | Criteria Details |
|------------------------------|------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | Must be 2 years of age or younger. |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VITRAKVI

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VIZIMPRO

Products Affected

- VIZIMPRO

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VONJO

Products Affected

- VONJO

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Criteria will be applied consistent with current NCCN guidance. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VORANIGO

Products Affected

- VORANIGO ORAL TABLET 10 MG, 40 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 | |
| Part B Prerequisite | No |

voriconazole

Products Affected

- *voriconazole intravenous*

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VOWST

Products Affected

- VOWST

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Documentation of at least 2 recurrent episodes of CDI (3 or more total CDI episodes) after failure of appropriate antibiotic treatments. |
| Age Restrictions | Patient must be 18 years of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | 1 year. Limited to 1 treatment course (12 capsules over 3 days). |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| 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 reauthorization: Must have documentation of a positive clinical response as determined by the prescriber. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VOYDEYA

Products Affected

- VOYDEYA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Voydeya is not covered in combination with Fabhalta or Empaveli. |
| Required Medical Information | For initial requests: (1) Must have diagnosis of PNH confirmed by flow cytometry, (2) must be actively receiving treatment with Ultomiris/Soliris and considered stable (defined as treatment for at least 6 months) -AND- (3) Must have symptomatic extravascular hemolysis defined as: Fatigue or dyspnea - AND - Hgb less than 9.5g/dL, OR Absolute Reticulocyte Count greater than 120 x 10 ⁹ /L. |
| Age Restrictions | Must be age 18 years or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and reauthorization. |
| Other Criteria | For reauthorization: (1) must be actively receiving treatment with Ultomiris/Soliris, AND (2) must have documentation of improvement in EVH symptoms (e.g., fatigue, dyspnea), AND (3) must have a sustained increase in hemoglobin levels, improvement in hemolysis, or reduced transfusions compared to baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VYNDAMAX

Products Affected

- VYNDAMAX

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with TTR-lowering agents (e.g., Amvuttra, Tegsedi, Onpattro). |
| Required Medical Information | Coverage requires (1) A diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) confirmed by tissue biopsy, genetic testing, or radionuclide imaging(99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided) - and - (2) Presence of signs or symptoms of cardiomyopathy and heart failure (e.g.,dyspnea, edema, angina) - and (3) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake - and - either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). |
| Age Restrictions | Must be age 18 or older |
| Prescriber Restrictions | |
| Coverage Duration | One year initial. Two years reauthorization. |
| Other Criteria | Vyndamax will not be approved if the patient has primary (light-chain) amyloidosis. For reauthorization requests, coverage requires documentation of a positive clinical response to Vyndamax compared to baseline (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

VYNDAQEL

Products Affected

- VYNDAQEL

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with TTR-lowering agents (e.g., Amvuttra, Tegsedi, Onpattro). |
| Required Medical Information | Coverage requires (1) A diagnosis of transthyretin amyloid cardiomyopathy (ATTR-CM) confirmed by tissue biopsy, genetic testing, or radionuclide imaging (99mTc-PYP, 99mTc-DPD, or 99mTc-HMDP scan) (documentation must be provided) - and - (2) Presence of signs or symptoms of cardiomyopathy and heart failure (e.g., dyspnea, edema, angina) - and (3) if the diagnosis was confirmed by radionuclide imaging, coverage also requires documentation of Grade 2 or 3 cardiac uptake - and - either an echocardiogram (ECHO) or cardiac magnetic resonance (CMR) imaging demonstrating cardiac involvement (i.e., increased left ventricular wall thickness). |
| Age Restrictions | Must be age 18 or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year initial. Two years reauthorization. |
| Other Criteria | Vyndaqel will not be approved if the patient has primary (light-chain) amyloidosis. For reauthorization requests, coverage requires documentation of a positive clinical response to Vyndaqel compared to baseline (e.g., reduced cardiovascular-related hospitalizations, improved function, improved quality of life). |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

WAINUA

Products Affected

- WAINUA

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with tafamidis (Vyndaqel, Vyndamax), or other TTR-lowering agents (Tegsedi, Onpattro, Amvuttra). |
| Required Medical Information | For hereditary transthyretin-mediated amyloidosis (hATTR) with polyneuropathy, must have (1) confirmation of a transthyretin (TTR) mutation on genetic test, (2) presence of clinical signs and symptoms of the condition (e.g., motor disability, peripheral/autonomic neuropathy, etc.), and (3) documentation of a baseline FAP Stage 1 or 2. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year initial and reauthorization. Dosing must align with FDA-approved labeling. |
| Other Criteria | Patient must not have had a liver transplant. For reauthorization, must also have documentation of a positive clinical response to Wainua 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 | |
| Part B Prerequisite | No |

WELIREG

Products Affected

- WELIREG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

WINREVAIR

Products Affected

- WINREVAIR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | For initial requests, documentation of the following is required: (1) Must have a confirmed diagnosis of Pulmonary Arterial Hypertension (PAH), World Health Organization Group 1, by right heart catheterization, AND (2) Must have WHO functional class II or III symptoms, AND (3) Must have tried and failed (defined as an inability to improve the condition) of dual therapy with a phosphodiesterase inhibitor (e.g., sildenafil or tadalafil) AND an endothelin receptor antagonist (e.g., ambrisentan or bosentan), AND (4) Winrevair will be initiated as add on therapy to at least 2 other PAH agents (e.g. ERA, PDE5i, Prostaglandins). |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a specialist for the condition. |
| Coverage Duration | Initial: 1 year. Reauth: 2 years. |
| Other Criteria | For reauthorization requests: Documentation must be provided demonstrating that the patient has had a beneficial response to Winrevair compared to pretreatment baseline in one or more of the following: improvement in WHO functional class, risk status, or 6MWD. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XALKORI

Products Affected

- XALKORI ORAL CAPSULE
- XALKORI ORAL CAPSULE SPRINKLE 150 MG, 20 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XATMEP

Products Affected

- XATMEP

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | Must try and fail (defined as an intolerance or inability to improve the condition) generic methotrexate. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XDEMVY

Products Affected

- XDEMVY

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Diagnosis of Demodex blepharitis confirmed by the presence of mites on examination by light microscopy or presence of collarettes on slit lamp examination. |
| Age Restrictions | Must be at least 18 years of age. |
| Prescriber Restrictions | Must be prescribed by or in consultation with an optometrist or ophthalmologist. |
| Coverage Duration | One year. |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XELJANZ

Products Affected

- XELJANZ ORAL TABLET

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XELJANZ SOLUTION

Products Affected

- XELJANZ ORAL SOLUTION

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XELJANZ XR

Products Affected

- XELJANZ XR

| PA Criteria | Criteria Details |
|-------------------------------------|---|
| Exclusion Criteria | Must not be used in combination with other biological drugs or Otezla. |
| Required Medical Information | 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 | Two years. Dosing must follow the FDA-approved labeling. |
| Other Criteria | For RA: Must try and fail (defined as an intolerance or inability to improve symptoms) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine). For PsA: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., methotrexate, leflunomide, sulfasalazine). For UC: Must try and fail (defined above) one traditional non-biologic immunomodulator drug (e.g., 6-mercaptopurine, azathioprine, cyclosporine) or a steroid (e.g., prednisone). For ankylosing spondylitis: Must try and fail (defined above) one nonsteroidal anti-inflammatory drug (NSAID). For Juvenile Idiopathic Arthritis: Must try and fail (defined above) one other drug for the condition (e.g., methotrexate, sulfasalazine, NSAID) - or - the patient will be starting Xeljanz XR concurrently with methotrexate, sulfasalazine, or leflunomide - or - the patient has aggressive disease, as determined by the prescribing physician. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Patient must have been receiving stable dose SSA therapy (either long-acting release (LAR), depot, or infusion pump) for at least 3 months. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XGEVA

Products Affected

- XGEVA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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. Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit. |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

XIFAXAN

Products Affected

- XIFAXAN ORAL TABLET 200 MG, 550 MG

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | For IBS-D, no more than a total of three, 14-day treatment courses are covered. |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | IBS-D initial: 14 days. IBS-D reauth: 14 days. TD: 3 days. All others: 2 years. |
| Other Criteria | For travelers diarrhea (TD): Coverage requires a trial and failure (defined as an intolerance or inability to improve the condition) with azithromycin. For hepatic encephalopathy: Coverage requires a trial and failure (defined above) with lactulose. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XOLAIR

Products Affected

- XOLAIR

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with other biologic drugs. |
| Required Medical Information | Documentation of prior therapies and responses to treatment. For asthma, nasal polyps: Must provide patient's current weight and baseline IgE level. For food allergy requests, the following must also be met for approval: (1) Patient has a diagnosis of an IgE-mediated food allergy confirmed by both a positive in vitro test for IgE to the specified foods AND a positive skin prick test to the specified foods, AND (2) Patient has a clinical history of a significant allergic reaction to the specified foods, AND (3) Patient has a baseline IgE level of at least 30 IU/mL, AND (4) Xolair must be used in conjunction with a food allergen-avoidant diet, AND (5) Patient's current weight and baseline IgE level have been provided, AND (6) Patient is at least 1 year of age. For food allergy reauthorization requests: (1) Xolair must continue to be used in conjunction with a food allergen-avoidant diet, AND (2) the patient's current weight and baseline IgE level must be provided. |
| 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 reauth (food allergy). 2 years (others). Dose must follow FDA-approved labeling. |

| PA Criteria | Criteria Details |
|----------------------------|--|
| Other Criteria | <p>For asthma: Must try and fail with 1 ICS/LABA inhaler drug 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).</p> <p>For nasal polyps: Must try and fail (defined as an inability to improve symptoms for least 8 weeks) with intranasal steroids - AND - Must be used in combination with an intranasal steroid - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). For chronic urticaria: Must try and fail (defined as an intolerance or inability to improve symptoms) with at least one H1 antihistamine (e.g., levocetirizine, desloratadine) - and - for reauthorization, must have documented clinical benefit (e.g. decrease in exacerbations, improvement in symptoms, decrease in steroid use). Diagnosis and administration information will be reviewed to determine if coverage is available as a Medicare Part B or Part D benefit.</p> |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XOSPATA

Products Affected

- XOSPATA

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

XPOVIO

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZEJULA

Products Affected

- ZEJULA ORAL CAPSULE
- ZEJULA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZELBORAF

Products Affected

- ZELBORAF

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZEMAIRA

Products Affected

- ZEMAIRA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | Patient must have an FEV1 less than 80 percent predicted - AND - a 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 | Two years |
| Other Criteria | |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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 | |
| Part B Prerequisite | No |

ZILBRYSQ

Products Affected

- ZILBRYSQ SUBCUTANEOUS SOLUTION
 PREFILLED SYRINGE 16.6 MG/0.416ML,
 23 MG/0.574ML, 32.4 MG/0.81ML

| PA Criteria | Criteria Details |
|-------------------------------------|--|
| Exclusion Criteria | Must not be used in combination with similar therapies for myasthenia gravis including immune globulins, Soliris, Ultomiris, Vyvgart/Vygart Hytrulo, or Rystiggo. (Zilbrysq has not been studied and there is no data to support use in combination with other medications used to treat MG). |
| Required Medical Information | For initial requests, must have: (1) Confirmed generalized myasthenia gravis that is anti-acetylcholine receptor antibody (AChR-Ab) positive - AND - (2)baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) of 6 or more - AND - (3) trial and failure (defined as an intolerance or inability to improve the condition) of Vyvgart or Rystiggo - AND - (4) trial and failure (defined above) of Ultomiris. For initial and reauthorization: Medical records supporting the request must be provided. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | Must be prescribed by or in consultation with a neurologist. |
| Coverage Duration | 12 weeks (initial), 1 year (reauth) |
| Other Criteria | For reauthorization: Must have a documented response to therapy evidenced by a stable or improved MG-ADL total score from baseline. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | Yes |

ZOLINZA

Products Affected

- ZOLINZA

| PA Criteria | Criteria Details |
|------------------------------|---|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| 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 | |
| Part B Prerequisite | No |

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 | Two years |
| 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 | |
| Part B Prerequisite | No |

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 | Two years |
| Other Criteria | Documented therapeutic failure of at least 2 previous antiepileptic drugs. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZURZUVAE

Products Affected

- ZURZUVAE ORAL CAPSULE 20 MG, 25 MG, 30 MG

| PA Criteria | Criteria Details |
|------------------------------|--|
| Exclusion Criteria | |
| Required Medical Information | Confirmation of diagnosis of postpartum depression. |
| Age Restrictions | Must be 18 years of age or older. |
| Prescriber Restrictions | |
| Coverage Duration | One year. Limited to one treatment course per year. |
| Other Criteria | Must follow current ACOG recommendations which require the patient to be in the postpartum period (ie, within 12 months postpartum) for depression that has onset in the third trimester or within 4 weeks postpartum. |
| Indications | All FDA-approved Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZYDELIG

Products Affected

- ZYDELIG

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

ZYKADIA

Products Affected

- ZYKADIA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------|-------------------------------------|
| Exclusion Criteria | |
| Required Medical Information | |
| Age Restrictions | |
| Prescriber Restrictions | |
| Coverage Duration | Two years |
| Other Criteria | |
| Indications | All Medically-accepted Indications. |
| Off Label Uses | |
| Part B Prerequisite | No |

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