

MCS Classicare 2024 Formulary 1 Prior Authorization Criteria

MCS Classicare Metro (HMO); MCS Classicare MAPD Groups (HMO-POS)

MCS Classicare requires you (or your physician) to get prior authorization for certain drugs. This means that you will need to get approval from MCS Classicare before you fill your prescriptions. If you don't get approval, MCS Classicare may not cover the drug.

MCS Classicare is an HMO plan subscribed by MCS Advantage, Inc.

ATTENTION: If you speak English, language assistance services, free of charge, are available to you. Call 1.866.627.8183 (TTY: 1.866.627.8182).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.627.8183 (TTY: 1.866.627.8182).

注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1.866.627.8183 (TTY: 1.866.627.8182).

Last Updated: 03/19/2024

H5577 2140723 C

Prior Authorization Requirements

ABIRATERONE

Products Affected

• abiraterone acetate oral tablet 250 mg, 500 mg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Castration-resistant metastatic prostate cancer (CRPC), or B.) High risk, castration-sensitive metastatic prostate cancer (CSPC). For treatment of CRPC and CSPC, abiraterone will be used in combination with prednisone AND one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, triptorelin), OR 2) Patient has received bilateral orchiectomy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ACITRETIN

Products Affected

• acitretin

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Severely impaired liver or kidney function, B.) Chronic abnormally elevated blood lipid values, C.) Concomitant use of methotrexate or tetracyclines, D.) Pregnancy |
| Required Medical Information | Diagnosis of severe, recalcitrant psoriasis (including plaque, guttate, erythrodermic palmar- plantar and pustular) AND patient must have tried and failed, contraindication or intolerance to one formulary first line agent (e.g., Topical Corticosteroids (betamethasone, fluocinonide, desoximetasone), Topical Calcipotriene/Calcitriol, Topical Calcipotriene, OR Topical Tazarotene) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a dermatologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ACTIMMUNE

Products Affected

• ACTIMMUNE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic granulomatous disease for use in reducing the frequency and severity of serious infections, or B.) Severe, malignant osteopetrosis (SMO) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ADALIMUMAB-ADBM

Products Affected

• adalimumab-adbm (2 pen)

- adalimumab-adbm(cd/uc/hs strt)
- adalimumab-adbm(ps/uv starter)
- adalimumab-adbm (2 syringe) subcutaneous prefilled syringe kit 10 mg/0.2ml, 20 mg/0.4ml, 40 mg/0.8ml

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non- infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ADEMPAS

Products Affected

• ADEMPAS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form, B.) Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline), C.) Pregnancy, or D.) Patients with pulmonary hypertension associated with idiopathic interstitial pneumonia |
| Required Medical Information | Diagnosis of one of the following A.) Pulmonary arterial hypertension (WHO group I) and diagnosis was confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.), or B.) Chronic thromboembolic pulmonary hypertension (CTEPH, WHO group 4) and patient has persistent or recurrent disease after surgical treatment (e.g., pulmonary endarterectomy) or has CTEPH that is inoperable (Female patients must be enrolled in the ADEMPAS REMS program) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | Initial: 6 months, Renewal: Plan Year |
| Other Criteria | Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AFINITOR

Products Affected

• everolimus oral tablet 10 mg, 2.5 mg, 5 mg, 7.5 mg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Hypersensitivity to everolimus, or B.) Hypersensitivity to rapamycin derivatives (e.g., sirolimus) |
| Required Medical Information | Diagnosis of one of the following A.) Renal angiomyolipoma and tuberous sclerosis complex (TSC) not requiring immediate surgery, B.) Advanced hormone receptor-positive, HER2 negative breast cancer in postmenopausal women and taken in combination with exemestane, after failure with letrozole or anastrozole, C.) Progressive, well-differentiated, nonfunctional neuroendocrine tumors of gastrointestinal or lung origin and disease is unresectable, locally advanced, or metastatic, D.) Pancreatic progressive neuroendocrine tumors and disease is unresectable, locally advanced renal cell carcinoma (RCC) after failure with sunitinib or sorafenib, F.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AKEEGA

Products Affected

• AKEEGA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) AND used in combination with prednisone |
| Age Restrictions | 18 years or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ALECENSA

Products Affected

• ALECENSA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic anaplastic lymphoma kinase (ALK) positive non- small cell lung cancer as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ALOSETRON

Products Affected

• alosetron hcl

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Constipation, B.) History of Chronic or severe constipation or sequelae from constipation, C.) History of ischemic colitis, intestinal obstruction, stricture, toxic megacolon, GI perforation, adhesions, diverticulitis, Crohn's disease, ulcerative colitis, D.) History of severe hepatic impairment, E.) History of impaired intestinal circulation, thrombophlebitis, or hypercoagulable state, or F.) Coadministration with fluvoxamine |
| Required Medical Information | Diagnosis of irritable bowel syndrome, severe diarrhea-predominant |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ALPHA-1 PROTEINASE INHIBITOR

Products Affected

• PROLASTIN-C

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Immunoglobulin A (IgA) deficiency with antibodies against IgA |
| Required Medical Information | Diagnosis of alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency in adult patients with emphysema |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ALUNBRIG

Products Affected

• ALUNBRIG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of anaplastic lymphoma kinase-positive (ALK) metastatic non- small cell lung cancer (NSCLC) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AMBRISENTAN

Products Affected

• ambrisentan

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Pregnancy, or B.) Idiopathic pulmonary fibrosis (IPF), including those with pulmonary hypertension |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension classified as WHO Group I, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | Initial: 6 months, Renewal: Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AMJEVITA

Products Affected

• AMJEVITA

• AMJEVITA-PED 15KG TO <30KG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non- infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

APTIOM

Products Affected

• APTIOM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of partial-onset seizures |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ARCALYST

Products Affected

• ARCALYST

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Cryopyrin-associated periodic syndromes (CAPS), including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells Syndrome (MWS), B.) Deficiency of interleukin-1 receptor antagonist (DIRA) and patient requires maintenance therapy for remission, or C.) Recurrent pericarditis (RP) and reduction in risk of recurrence |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ARIKAYCE

Products Affected

• ARIKAYCE

| DA Cuitonia | Criteria Details |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Known sensitivity to any aminoglycoside |
| Required Medical Information | Diagnosis of pulmonary Mycobacterium avium complex (MAC) infection and used as part of a combination antibacterial regimen in treatment refractory patients (greater than 6 months of a multidrug background regimen) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an infectious disease specialist or pulmonologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ATYPICALS

| | MTUFII. REXULTIJLAR PREFILLED. RISPERDAL CONSTAMG/2.4ML, 960. SECUADO. VERSACLOZ. VERSACLOZNTENA. VRAYLAR ORAL CAPSULE 1.5 MG, 3 MG, 4.5 MG, 6 MG. VRAYLAR ORAL CAPSULE |
|------------------------------------|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Select atypical antipsychotics will be covered when one the following is met A.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and the patient unable to take at least one generic oral atypical antipsychotic due to inadequate treatment response, intolerance, or contraindication, B.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient has a clinical condition for which there is no generic alternative or the generic alternatives are not recommended based on published guidelines or clinical literature, or C.) Patient is using the requested drug for an FDA-Approved or compendia supported indication and patient medically requires use of a specific dosage form that is not available in the generic alternatives (examples: suspension, solution, injection). |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AUGTYRO

Products Affected

• AUGTYRO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally advanced or metastatic ROS1-positive non-small cell lung cancer |
| Age Restrictions | 18 years or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• AUSTEDO

• AUSTEDO XR PATIENT TITRATION

 AUSTEDO XR ORAL TABLET EXTENDED RELEASE 24 HOUR 12 MG, 24 MG, 6 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Suicidal ideation and/or untreated or inadequately treated depression in a patient with Huntington's Disease, B.) Hepatic impairment, C.) Concomitant use of MAOIs, reserpine, tetrabenazine, or valbenazine |
| Required Medical Information | Diagnosis of one of the following A.) Chorea associated with Huntington's disease (Huntington's chorea), or B.) Tardive dyskinesia |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist or psychiatrist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

AYVAKIT

Products Affected

• AYVAKIT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Unresectable or metastatic gastrointestinal stromal tumor, with a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations, B.) Advanced Systemic Mastocytosis (AdvSM), including aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), or mast cell leukemia (MCL), and platelet count of at least 50,000/mcL, or C.) Indolent systemic mastocytosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist, allergist, or immunologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BALVERSA

Products Affected

BALVERSA ORAL TABLET 3 MG, 4
 MG, 5 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally advanced or metastatic urothelial carcinoma and both of the following 1.) Susceptible fibroblast growth factor receptor (FGFR)3 or FGFR2 genetic alterations confirmed by an FDA-approved diagnostic test, and 2.) Patient has progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BANZEL

Products Affected

• rufinamide oral tablet

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Familial Short QT Syndrome |
| Required Medical Information | Diagnosis of seizures associated with Lennox-Gastaut syndrome |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BENLYSTA

Products Affected

• BENLYSTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Active, autoantibody-positive, system lupus erythematosus (SLE), or B.) Active lupus nephritis and patient is receiving standard therapy |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a nephrologist or rheumatologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BESREMI

Products Affected

• BESREMI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Existence of, or history of severe psychiatric disorders (severe depression, suicidal ideation, or suicide attempt), B.) Hypersensitivity to interferons including interferon alfa-2b or excipients, C.) Hepatic impairment (Child-Pugh B or C), D.) History or presence of active serious or untreated autoimmune disease, or E.) Immunosuppressed transplant recipients |
| Required Medical Information | Diagnosis of polycythemia vera |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BEXAROTENE GEL

Products Affected

• bexarotene

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of primary cutaneous T-cell lymphoma (CTCL Stage 1A/1B) and patient had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) indicated for cutaneous manifestations of CTCL |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or dermatologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BEXAROTENE ORAL

Products Affected

• *bexarotene*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of cutaneous T-cell lymphoma (CTCL) and patient is not a candidate for or had an inadequate response, is intolerant to, or has a contraindication to at least one prior systemic therapy (e.g., corticosteroids) for cutaneous manifestations of CTCL |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist, hematologist, or dermatologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BOSENTAN

Products Affected

• bosentan

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Concomitant cyclosporine A or glyburide therapy, or B.) Pregnancy |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension (WHO Group I) and patient has New York Heart Association (NYHA) Functional Class II-IV, confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | Initial: 6 months, Renewal: Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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Products Affected

• BOSULIF ORAL CAPSULE 100 MG, 50 • BOSULIF ORAL TABLET 100 MG, 400 MG

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MG, 500 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic, accelerated, or blast phase Philadelphia chromosome-positive (Ph+) chronic myelogenous leukemia (CML) with resistance or inadequate response to prior therapy, or B.) Newly diagnosed chronic phase Philadelphia chromosome-positive (Ph+) CML |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BRAFTOVI

Products Affected

• BRAFTOVI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) unresectable or metastatic melanoma with documented BRAF V600E or V600K mutation as detected by a FDA- approved test and used in combination with binimetinib, B.) metastatic colorectal cancer with documented BRAF V600E mutation as detected by a FDA-approved test, patient has received prior therapy, and braftovi used in combination with cetuximab, or C.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test and used in combination with binimetinib |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BRIVIACT

Products Affected

• BRIVIACT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of partial-onset seizures, member must have history of inadequate response, contraindication, or intolerance to levetiracetam prior to approval. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BRONCHITOL

Products Affected

• BRONCHITOL

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Cystic fibrosis of the lung |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | Plan year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

BRUKINSA

Products Affected

• BRUKINSA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following: A.) mantle cell lymphoma (MCL) and patient has received at least one prior therapy, B.) Treatment of adult patients with Waldenstrom macroglobulinemia, C.) Treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen, D.) Chronic lymphocytic leukemia, or E.) Small lymphocytic lymphoma |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CABOMETYX

Products Affected

• CABOMETYX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Advanced hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib, C.) Advanced renal cell carcinoma and used as first line treatment in combination with nivolumab or D.) treatment of adults and pediatric patients 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CALQUENCE

Products Affected

CALQUENCE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Mantle cell lymphoma (MCL) and patient has received at least 1 prior therapy, B.) Chronic lymphocytic leukemia (CLL), or C.) Small lymphocytic lymphoma (SLL) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CAMZYOS

Products Affected

• CAMZYOS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of symptomatic New York Heart Association (NYHA) class II- III obstructive hypertrophic cardiomyopathy (HCM) in adult patients |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CAPRELSA

Products Affected

• CAPRELSA ORAL TABLET 100 MG, 300 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Congenital long QT syndrome |
| Required Medical Information | Diagnosis of metastatic or unresectable locally advanced medullary thyroid cancer (MTC) AND disease is symptomatic or progressive |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CARGLUMIC ACID

Products Affected

• carglumic acid

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) N-acetyl glutamate synthase (NAGS) deficiency (confirmed by appropriate genetic testing) with acute or chronic hyperammonemia, or B.) Propionic or methylmalonic acidemia with acute hyperammonemia |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CAYSTON

Products Affected

• CAYSTON

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has Pseudomonas aeruginosa lung infection confirmed by positive culture |
| Age Restrictions | 7 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• clobazam oral suspension

• SYMPAZAN

• clobazam oral tablet

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of seizures associated with Lennox-Gastaut syndrome |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CNS STIMULANTS

Products Affected

• armodafinil

• modafinil

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Obstructive sleep apnea (OSA) confirmed by sleep lab evaluation, B.) Narcolepsy confirmed by sleep lab evaluation, or C.) Shift work disorder (SWD) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

COMETRIQ

Products Affected

• COMETRIQ (100 MG DAILY DOSE)

• COMETRIQ (60 MG DAILY DOSE)

• COMETRIQ (140 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of progressive, metastatic medullary thyroid cancer |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

COPIKTRA

Products Affected

• COPIKTRA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Relapsed or refractory chronic lymphocytic leukemia (CLL), or B.) Relapsed or refractory small lymphocytic lymphoma (SLL). For CLL or SLL, the patient must have history of at least 2 prior therapies |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

CORLANOR ORAL SOLUTION
 CORLANOR ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Decompensated acute heart failure, B.) hypotension (i.e. blood pressure less than 90/50 mmHg), C.) sick sinus syndrome or sinoatrial block or 3rd degree AV block (unless a functioning demand pacemaker is present), D.) bradycardia (i.e., resting heart rate less than 60 bpm prior to treatment), E.) Severe hepatic impairment (Child- Pugh C), F.) Pacemaker dependent (heart rate maintained exclusively by the pacemaker), G.) Concomitant use of strong CYP3A4 inhibitors |
| Required Medical Information | Diagnosis of one of the following A.) Adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction 35% or less, who are in sinus rhythm with resting heart rate 70 beats per minute or more and either are on maximally tolerated doses of beta- blockers or have a contraindication to beta-blocker use, or B.) Pediatric patients with stable, symptomatic heart failure due to dilated cardiomyopathy and are in sinus rhythm with an elevated heart rate |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

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

COSENTYX UNOREADY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Ankylosing spondylitis, B.) Moderate to severe plaque psoriasis in adults, C.) Moderate to severe plaque psoriasis in patients 6 years to less than 18 years of age, D.) Active psoriatic arthritis in adult patients, E.) Active psoriatic arthritis in patients 2 years to less than 18 years of age, F.) Non-radiographic axial spondyloarthritis G.) Active enthesitis-related arthritis, or H.) Moderate to severe hidradenitis suppurativa in adults. Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

COTELLIC

Products Affected

• COTELLIC

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.)unresectable or metastatic malignant melanoma with BRAF V600E OR V600K mutation, and documentation of combination therapy with vemurafenib (Zelboraf), or B.) Histiocytic neoplasms |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

CYSTAGON

Products Affected

• CYSTAGON

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Known serious hypersensitivity to penicillamine or cysteamine |
| Required Medical Information | Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DALFAMPRIDINE

Products Affected

• dalfampridine er

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) History of seizure. B.) Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute) |
| Required Medical Information | Diagnosis of multiple sclerosis and patient must demonstrate sustained walking impairment, but with the ability to walk 25 feet (with or without assistance) prior to starting dalfampridine |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DAURISMO

Products Affected

• DAURISMO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of newly diagnosed acute myeloid leukemia (AML) and used in combination with cytarabine in patients 75 years of age or older OR in patients that have comorbidities that preclude use of intensive induction chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an Oncologist or Hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DAYBUE

Products Affected

• DAYBUE

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Rett syndrome |
| Age Restrictions | 2 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DEFERASIROX

Products Affected

• deferasirox

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Creatinine clearance less than 40 mL/min, B.) Poor performance status, C.) Platelet count less than 50 x 10(9)/L, D.) Advanced malignancy, E.) High-risk myelodysplastic syndrome (MDS) |
| Required Medical Information | Diagnosis of one of the following A.) Chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes who have liver iron concentrations of at least 5 mg Fe/g dry weight AND serum ferritin level greater than 300 mcg/L, or B.) Chronic iron overload due to blood transfusions (transfusion hemosiderosis) as evidenced by transfusion of at least 100 mL/kg packed red blood cells AND serum ferritin level greater than 1000 mcg/L |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DEFERIPRONE

Products Affected

• deferiprone

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) Diagnosis of transfusional iron overload due to thalassemia syndromes, sickle cell disease, or other anemias, 2.) Patient has failed prior chelation therapy, and 3.) Patient has an absolute neutrophil count greater than $1.5 \times 10(9)/L$ |
| Age Restrictions | 8 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DIACOMIT

Products Affected

• DIACOMIT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of severe myoclonic epilepsy in infancy (Dravet syndrome) in patients taking clobazam |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DICLOFENAC PATCH

Products Affected

• diclofenac epolamine

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of acute mild to moderate pain due to minor strains, sprains and contusions |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 3 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DIMETHYL FUMARATE

Products Affected

• dimethyl fumarate

• *dimethyl fumarate starter pack*

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DOJOLVI

Products Affected

• DOJOLVI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Long-chain fatty acid oxidation disorder (LC-FAOD) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DRONABINOL

Products Affected

• dronabinol

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Sesame oil hypersensitivity |
| Required Medical Information | Diagnosis of one of the following A.) Anorexia associated to AIDS, or B.) Chemotherapy-induced nausea and vomiting |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DROXIDOPA

Products Affected

• droxidopa

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (e.g., Parkinson disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Initial: 1 month, Renewal: 3 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

DUPIXENT

Products Affected

• DUPIXENT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe atopic dermatitis and if patient is 2 years or older has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid and/or 2.) Topical calcineurin inhibitor, B.) Eosinophilic phenotype or oral corticosteroid-dependent moderate to severe asthma and used as an adjunct treatment, or C.) Chronic rhinosinusitis with nasal polyposis and used as an adjunct treatment, D.) Eosinophilic esophagitis, or E.) Prurigo nodularis |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an allergist, dermatologist, gastroenterologist, immunologist, otolaryngologist, pulmonologist, or rheumatologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EMGALITY

Products Affected

• EMGALITY

• EMGALITY (300 MG DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic or episodic migraine disorder and patient has documented trial, inadequate response, or contraindication to at least 2 generic formulary drugs used for migraine prevention (i.e., propranolol, topiramate, divalproex, timolol), or B.) Episodic cluster headache |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EMSAM

Products Affected

• EMSAM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Concomitant use with any of the following: SSRIs, SNRIs, clomipramine, imipramine, meperidine, tramadol, methadone, pentazocine, propoxyphene, dextromethorphan, carbamazepine, or B.) Pheochromocytoma |
| Required Medical Information | Diagnosis of major depressive disorder and patient had trial of at least 2 generic oral antidepressants from differing classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), unless unable to take any oral medication AND Patient had an adequate washout period (for patients previously on agents requiring a washout period) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ENBREL

- ENBREL
- ENBREL MINI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, or E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• ENBREL SURECLICK

ENDARI

Products Affected

• ENDARI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of sickle cell disease AND one of the following 1.) Patient has acute complications and is being treated with Hydroxyurea, or 2.) Patient has acute complications and is unable to tolerate Hydroxyurea |
| Age Restrictions | 5 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ENSPRYNG

Products Affected

• ENSPRYNG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Active Hepatitis B infection, or B.) Active or untreated latent tuberculosis |
| Required Medical Information | Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) in patients who are anti-aquaporin-4 (AQP4) antibody positive |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist, immunologist, or ophthalmologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EPIDIOLEX

Products Affected

• EPIDIOLEX

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Lennox-Gastaut syndrome, B.) Severe myoclonic epilepsy in infancy (Dravet syndrome), or C.) Seizures associated with tuberous sclerosis complex (TSC) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EPOETIN THERAPY

Products Affected

• RETACRIT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Pretreatment hemoglobin levels of less than 10g/dL. Dose reduction or interruption if hemoglobin exceeds 10 g/dL (CKD not on dialysis-adult, cancer), 11 g/dL (CKD on dialysis), 12 g/dL (pediatric CKD) in addition to supporting statement of diagnosis from physician. Patients with perioperative hemoglobin more than 10 g/dL to 13 g/dL scheduled to undergo elective, noncardiac, nonvascular surgery |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 3 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ERIVEDGE

Products Affected

• ERIVEDGE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic basal cell carcinoma, or B.) Locally advanced basal cell carcinoma that has recurred following surgery or the patient is not a candidate for surgery or radiation |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ERLEADA

Products Affected

• ERLEADA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Nonmetastatic, castration-resistant prostate cancer (nmCRPC), or B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of nmCRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, OR 2) Patient has received bilateral orchiectomy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ERLOTINIB

Products Affected

• erlotinib hcl

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, B.) Locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND one of the following 1.) Erlotinib will be used as first-line treatment, 2.) Failure with at least one prior chemotherapy regimen, OR 3.) No evidence of disease progression after four cycles of first-line platinum-based chemotherapy and erlotinib will be used as maintenance treatment |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EVEROLIMUS SUSPENSION

Products Affected

 everolimus oral tablet soluble 2 mg, 3 mg, 5 mg

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Hypersensitivity to everolimus, or B.) Hypersensitivity to rapamycin derivatives (e.g. sirolimus) |
| Required Medical Information | Diagnosis of one of the following A.) Tuberous sclerosis complex (TSC)- associated partial-onset seizures, or B.) Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex in patients who are not candidates for curative surgical resection |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EVRYSDI

Products Affected

• EVRYSDI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of spinal muscular atrophy (SMA) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

EXKIVITY

Products Affected

• EXKIVITY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations (as confirmed by an FDA-approved test) AND whose disease has progressed on or after platinum-based chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FASENRA

Products Affected

• FASENRA

• FASENRA PEN

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of severe asthma with an eosinophilic phenotype |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FEBUXOSTAT

Products Affected

• febuxostat

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concomitant use of azathioprine or mercaptopurine |
| Required Medical Information | Diagnosis of Gout and all of the following 1.) documented inadequate treatment response, adverse event, or contraindication to maximally titrated dose of Allopurinol, and 2.) patients with established cardiovascular disease, prescriber attests that benefit of treatment outweighs the risk of treatment |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FENTANYL ORAL

Products Affected

• *fentanyl citrate*

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Management of acute or postoperative pain (including headache/migraine, dental pain, and use in the emergency room), B.) Use in opioid non-tolerant patients, C.) Known or suspected gastrointestinal obstruction, including paralytic ileus, D.) Acute or severe bronchial asthma and used in an unmonitored setting (absence of resuscitative equipment) |
| Required Medical Information | Must meet all of the following 1.) Diagnosis of cancer-related breakthrough pain, 2.) Patient is currently receiving/tolerant to around-the- clock opioid therapy for persistent cancer pain, and 3.) Patient and prescriber are enrolled in the TIRF REMS Access Program |
| Age Restrictions | 16 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FILSPARI

Products Affected

• FILSPARI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Pregnancy or B.) Concomitant use with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren |
| Required Medical Information | Diagnosis of treatment of primary immunoglobulin A (IgA) nephropathy at risk of rapid disease progression, generally a urine protein to creatinine ratio (UPCR) of 1.5 g/g or more, to reduce proteinuria |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FINTEPLA

Products Affected

• FINTEPLA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI |
| Required Medical Information | Diagnosis of Severe myoclonic epilepsy in infancy (Dravet syndrome) or seizures associated with Lennox-Gastaut syndrome |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FIRMAGON

Products Affected

• FIRMAGON

• FIRMAGON (240 MG DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced prostate cancer |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FOTIVDA

Products Affected

• FOTIVDA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsed or refractory advanced renal cell cancer (RCC) following 2 or more prior systemic therapies |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FRUZAQLA

Products Affected

• FRUZAQLA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic colorectal cancer (mCRC) and all of the following: A.) patient has been previously treated with fluoropyrimidine, oxaliplatin, irinotecan-based chemotherapy, B.) an anti-VEGF therapy, and C.) if RAS wild-type and medically appropriate, patient has also been previously treated with anti-EGFR therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 3 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FULPHILA

Products Affected

• FULPHILA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

FYCOMPA

Products Affected

• FYCOMPA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Partial-onset seizures with or without secondary generalization, or B.) Primary generalized tonic-clonic seizure disorder as adjunctive therapy |
| Age Restrictions | 4 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

GAVRETO

Products Affected

• GAVRETO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic RET fusion-positive non- small cell lung cancer (NSCLC) as detected by an FDA approved test, B.) Advanced or metastatic RET-mutant medullary thyroid cancer and patient requires systemic therapy, or C.) Advanced or metastatic RET fusion- positive thyroid and patient requires systemic therapy and is radioactive iodine-refractory, when radioactive iodine is appropriate |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

GEFITINIB

Products Affected

• gefitinib

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) and must meet all of the following 1.) Tumor has epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility and 2.) Used as first-line treatment |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

GILOTRIF

Products Affected

• GILOTRIF

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test, or B.) Metastatic squamous NSCLC with progression after platinum-based chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

GLATIRAMER

Products Affected

• glatiramer acetate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

GLEOSTINE

Products Affected

• GLEOSTINE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet one of the following: A.) Hodgkin's disease in patient who has relapsed during or failed to respond to primary therapy and is being used in combination with other agents OR B.) Intracranial tumor |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• OZEMPIC (0.25 OR 0.5 MG/DOSE)

RYBELSUS

OZEMPIC (1 MG/DOSE)OZEMPIC (2 MG/DOSE)

| ٠ | TRULICITY | |
|---|-----------|--|
| | | |

PA Criteria Criteria Details None **Exclusion** Criteria Required Must meet all of the following 1.) The drug is prescribed for an FDA-Medical approved indication, 2.) For a diagnosis of Type 2 Diabetes Mellitus the patient has a trial and failure, contraindication or intolerance to metformin Information or any metformin combination product None Age Restrictions Prescriber None **Restrictions** Coverage 12 months **Duration Other Criteria** None Indications All Medically-accepted Indications. **Off-Label Uses** N/A Part B No Prerequisite

GROWTH HORMONE

Products Affected

• OMNITROPE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Use for growth promotion in pediatric patients with closed epiphyses, B.) Acute critical illness caused by complications following open-heart or abdominal surgery, multiple accidental trauma, or acute respiratory failure, C.) Active malignancy, D.) Active proliferative or severe nonproliferative diabetic retinopathy, E.) Prader-Willi Syndrome in patients who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment |
| Required Medical Information | Supporting statement of diagnosis from the physician |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist or nephrologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HEPATITIS B

Products Affected

- adefovir dipivoxil
- BARACLUDE

- entecavir •
- VEMLIDY •

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of chronic hepatitis B and all of the following 1.) Patient has or had evidence of viral replication prior to initiation, 2.) Patient has evidence of persistent elevations in serum aminotransferase (ALT or AST) or histologically active disease, and 3.) Patient is receiving anti-retroviral therapy if the patient has HIV co-infection |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HEPATITIS C

Products Affected

• MAVYRET

• sofosbuvir-velpatasvir

| • sojosbuvir-veipaiasvir | |
|------------------------------------|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Must submit documentation of chronic hepatitis C genotype (confirmed by HCV RNA level within the last 6 months). Must submit laboratory results within 12 weeks prior to initiating therapy including: 1) CBC w Platelets, 2) AST/ALT, 3) Total Bilirubin, 4) Serum Albumin, and 5) PT/INR. Must include subtype, trial/failure, contraindication to, or intolerance to Sofosbuvir/Velpatasvir or Mavyret prior to approval of Vosevi. Genotype and subtype are not required for: (1) initial treatment of patients without cirrhosis if using Sofosbuvir-Velpatasvir or Mavyret OR (2) treatment of patients with compensated cirrhosis if using Mavyret |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| Coverage Duration | Duration of approval per AASLD Guidelines |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• VOSEVI

HRM - ANALGESICS

Products Affected

• butalbital-acetaminophen

• butalbital-apap-caffeine

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTI-ARRHYTHMICS

Products Affected

• digoxin oral solution

• digoxin oral tablet 250 mcg

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary Non HRM alternatives: propranolol, sotalol, dofetilide, amiodarone, propafenone, mexiletine |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTICHOLINERGIC

Products Affected

• chlordiazepoxide-clidinium

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTIDEMENTIA

Products Affected

• ergoloid mesylates

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary non-HRM alternatives: donepezil, galantamine, memantine, rivastigmine oral |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTIDEPRESSANTS

Products Affected

• chlordiazepoxide-amitriptyline

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary non-HRM alternatives: mirtazapine, trazodone, fluoxetine, escitalopram, fluvoxamine, desvenlafaxine, duloxetine, sertraline, venlafaxine, bupropion |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTIHISTAMINES

Products Affected

- hydroxyzine hcl
- hydroxyzine pamoate

- promethazine hcl
- PROMETHEGAN

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary non-HRM alternatives FOR MANAGEMENT OF ALLERGIC CONDITIONS: desloratadine, cetirizine syp, levocetirizine. FOR MANAGEMENT OF ANXIETY/SEDATION: buspirone, trazodone. FOR MANAGEMENT OF NAUSEA/VOMITING: granisetron, ondansetron |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - ANTIPARKINSON AGENTS

Products Affected

• *benztropine mesylate*

• trihexyphenidyl hcl

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary non-HRM alternatives: amantadine, carbidopa/levodopa, entacapone, Neupro, pramipexole, ropinirole, selegiline |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - BENZODIAZEPINES

Products Affected

alprazolam oral tablet 0.25 mg, 0.5 mg, 1
 mg, 2 mg

• chlordiazepoxide hcl

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

estazolam

temazepam

HRM - CARDIOVASCULAR

Products Affected

• guanfacine hcl er

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary Non HRM alternatives: atomoxetine, dexmethylphenidate, methylphenidate |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - MEGESTROL

Products Affected

• megestrol acetate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary Non HRM alternatives: dronabinol |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - SEDATIVE HYPNOTICS

Products Affected

• zaleplon

• *zolpidem tartrate*

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary non-HRM alternatives: Belsomra, doxepin 3mg and 6mg tablets, trazodone |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HRM - SKELETAL MUSCLE RELAXANTS

Products Affected

• cyclobenzaprine hcl

• orphenadrine citrate er

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) The drug is being prescribed for an FDA-approved indication, 2.) Patient has tried and failed at least one non-HRM alternative, 3.) The prescribing physician attests to the medical necessity for using this high risk medication. |
| Age Restrictions | Automatic approval if member is less than 65 years of age. Prior Auth required for age 65 or older. |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Formulary Non HRM alternatives: baclofen |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

| 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-CD/UC/HS STARTER HUMIRA-CD/UC/HS STARTER HUMIRA-PED>/=40KG CROHNS START HUMIRA-PED>/=40KG UC STARTER HUMIRA-PS/UV/ADOL HS STARTER HUMIRA-PSORIASIS/UVEIT STARTER | |
|--|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, D.) Ankylosing spondylitis, E.) Moderate to severe chronic plaque psoriasis in patients who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate, F.) Moderate to severe Crohn's disease in patients who have had an inadequate response to conventional therapy, G.) Moderate to severe ulcerative colitis in patients who have had an inadequate response to immunosuppressants (e.g. corticosteroids, azathioprine), H.) Non- infectious uveitis (including intermediate, posterior, and panuveitis), or I.) Moderate to severe hidradenitis suppurativa |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|------------------------|------------------|
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

HYFTOR

Products Affected

• HYFTOR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Facial angiofibroma associated with tuberous sclerosis |
| Age Restrictions | 6 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

IBRANCE

Products Affected

• IBRANCE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)- negative breast cancer used in combination with fulvestrant and disease has progressed following endocrine therapy, or B.) Advanced or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and used in combination with an aromatase inhibitor in a male or female patient as initial endocrine-based therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ICATIBANT

Products Affected

• *icatibant acetate*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hereditary angioedema AND medication will be used for the treatment of acute attacks |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an allergist, hematologist, or immunologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic phase, accelerated phase, or blast phase chronic myeloid leukemia (CML) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated, B.) Chronic phase, chronic myeloid leukemia (CML) in adult patients with resistance or intolerance to at least two prior kinase inhibitors, or C.) Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) in adult patients who are T315I-positive or for whom no other tyrosine kinase inhibitor therapy is indicated |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

IDHIFA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase 2 (IDH2) mutation as detected by an FDA approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

IMATINIB

Products Affected

• *imatinib mesylate oral tablet 100 mg, 400 mg*

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), B.) Ph+ acute lymphoblastic leukemia (ALL), C.) Gastrointestinal stromal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, D.) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, E.) Hypereosinophilic syndrome or chronic eosinophilic leukemia, F.) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G.) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

IMBRUVICA

Products Affected

Г

• IMBRUVICA ORAL CAPSULE 140 MG, 70 MG

1

• IMBRUVICA ORAL SUSPENSION

• IMBRUVICA ORAL TABLET

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL), B.) Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion, C.) Waldenstrom's macroglobulinemia (WM), or D.) Chronic graft vs host disease (cGVHD) after failure of at least one first-line corticosteroid therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INCRELEX

Products Affected

• INCRELEX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Active or suspected malignancy, B.) Use for growth promotion in patients with closed epiphyses, or C.) Intravenous administration |
| Required Medical Information | Diagnosis of one of the following A.) Severe primary insulin-like growth factor-1 (IGF-1) deficiency and utilized for pediatric treatment of growth failure, or B.) Growth hormone (GH) gene deletion and patient has developed neutralizing antibodies to GH and utilized for pediatric treatment of growth failure |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INJECTABLE TESTOSTERONE

Products Affected

• testosterone cypionate

• testosterone enanthate

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate, C.) Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, B.) Inoperable metastatic breast cancer in women who are postmenopausal (testosterone enanthate), C.) Primary hypogonadism, or D.) Delayed puberty (testosterone enanthate). Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INLYTA

Products Affected

• INLYTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma and patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens), or B.) Advanced renal cell carcinoma and used as first-line therapy in combination with avelumab or pembrolizumab |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INQOVI

Products Affected

• INQOVI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML]) and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INREBIC

Products Affected

• INREBIC

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of intermediate-2 or high-risk primary or secondary (post- polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF). |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

INTRAROSA

Products Affected

• INTRAROSA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Vaginal bleeding or dysfunctional uterine bleeding of an undetermined origin, or B.) Known or suspected estrogen- dependent neoplasia |
| Required Medical Information | Diagnosis of one of the following A.) moderate to severe dyspareunia due to menopause, or B.) atrophic vaginitis due to menopause |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Initial: 3 months, Renewal: 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

INVEGA HAFYERA
 INTRAMUSCULAR SUSPENSION

PREFILLED SYRINGE 1092 MG/3.5ML, 1560 MG/5ML

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months or Invega Trinza for at least one three-month injection cycle |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an psychiatrist |
| Coverage Duration | 12 months |
| Other Criteria | For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

 INVEGA SUSTENNA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE 117 MG/0.75ML, 156 MG/ML, 234 MG/1.5ML, 39 MG/0.25ML, 78 MG/0.5ML

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet one of the following A.) Diagnosis of schizophrenia and all of the following 1.) trial and failure, contraindication, or intolerance to two oral second-generation antipsychotics, 2.) Trial and failure to respond to haloperidol decanoate and fluphenazine decanoate, 3.)Member has established response and tolerability to oral paliperidone, and 4.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence, or B.) Diagnosis of schizoaffective disorder and both of the following 1.)Member has established response and tolerability to oral paliperidone and 2.) Patient presents history of noncompliance with oral medications and documentation is provided on the efforts to improve medication adherence |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an psychiatrist |
| Coverage Duration | 12 months |
| Other Criteria | For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Prior Authorization Criteria

MCS Classicare Formulary 1 – Formulary ID: 24445 – Version 11 Effective date: 04/01/2024 Last Updated: 03/19/2024

INVEGA TRINZA

Products Affected

• INVEGA TRINZA INTRAMUSCULAR SUSPENSION PREFILLED SYRINGE

273 MG/0.88ML, 410 MG/1.32ML, 546 MG/1.75ML, 819 MG/2.63ML

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following A.) Diagnosis of schizophrenia, and B.) Adequate treatment has been established with Invega Sustenna for at least 4 months |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an psychiatrist |
| Coverage Duration | 12months |
| Other Criteria | For continuation of therapy member must be re-evaluated by the psychiatrist to assess clinical response. Treatment should be discontinued if failure to therapy or an adverse event is documented or the member does not demonstate adherence to treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ITRACONAZOLE

Products Affected

• itraconazole

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Ventricular dysfunction (e.g., congestive heart failure (CHF) or history of CHF), B.) Concurrent therapy with a CYP3A4 substrate (e.g., methadone, lovastatin, simvastatin, etc.), C.) Concurrent use of CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, quinidine, terbinafine), D.) Renal or hepatic impairment and concomitant use of colchicine, fesoterodine, solifenacin, or telithromycin, E.) Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), or B.) Onychomycosis confirmed by one of the following: positive potassium hydroxide (KOH) preparation, fungal culture, or nail biopsy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

IVERMECTIN

Products Affected

• *ivermectin*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Prevention or treatment of COVID-19 |
| Required Medical Information | Diagnosis of one of the following: A.) Strongyloidiasis of the intestinal tract or B.) Onchocerciasis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 1 month |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

IWILFIN

Products Affected

• IWILFIN

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of high-risk neuroblastoma to be used to reduce the risk of relapse in adult and pediatric patients who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti- GD2 immunotherapy |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

JAKAFI

Products Affected

• JAKAFI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| | |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis, B.) Polycythemia vera AND patient has had an inadequate response to or is intolerant of hydroxyurea, C.) Acute graft versus host disease AND disease is refractory to steroid therapy, or D.) Chronic graft-versus-host disease (cGVHD) after failure of corticosteroid therapy (alone or in combination with a calcineurin inhibitor) and up to one additional line of systemic therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

JAYPIRCA

Products Affected

JAYPIRCA ORAL TABLET 100 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) relapsed or refractory mantle cell lymphoma (MCL) and is being used after at least two lines of systemic therapy, including a BTK inhibitor or B.) chronic lymphocytic leukemia or small lymphocytic lymphoma who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase inhibitor and a B-cell lymphoma 2 inhibitor. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

KALYDECO

Products Affected

• KALYDECO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis (CF) and the patient has 1 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

KERENDIA

Products Affected

• KERENDIA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | none |
| Required Medical Information | Diagnosis of Chronic kidney disease associated with Type 2 diabetes mellitus AND patient is currently receiving the following standard of care A.) A maximally tolerated dose of ACE inhibitor, ARB, or a combination medication containing an ACE or ARB AND B.) Antidiabetic agent (e.g., metformin or an agent containing metformin, SGLT2 inhibitor, GLP-1 RA) |
| Age Restrictions | none |
| Prescriber Restrictions | none |
| Coverage Duration | 12 months |
| Other Criteria | none |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

KINERET

Products Affected

• KINERET

| PA Criteria | Criteria Details |
|------------------------------------|--|
| r A Cinteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe active rheumatoid arthritis and patient has trial and failure, contraindication, or intolerance to two preferred products, (i.e. Humira, Enbrel, Orencia, Rinvoq), B.) Cryopyrin-associated periodic syndromes (i.e., neonatal-onset multisystem inflammatory disease), or C.) Deficiency of interleukin-1 receptor antagonist |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following A.) The patient is a pre-or perimenopausal woman or man and the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, B.) The patient is a postmenopausal woman or man, the requested drug will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), C.) The patient is a pre-or perimenopausal woman or man and the requested drug is being used with fulvestrant as initial endocrine- based therapy, or D.) The patient is a postmenopausal woman or man, the requested drug is being used following disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib), C.) The patient is a postmenopausal woman or man and the requested drug is being used following disease progression on endocrine therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• KISQALI (600 MG DOSE)

Prior Authorization Criteria

MCS Classicare Formulary 1 – Formulary ID: 24445 – Version 11 Effective date: 04/01/2024 Last Updated: 03/19/2024

KISQALI FEMARA

Products Affected

• KISQALI FEMARA (200 MG DOSE)

• KISOALI FEMARA (400 MG DOSE)

PA Criteria **Criteria Details Exclusion** None Criteria Diagnosis of advanced or metastatic hormone receptor (HR)-positive, Required Medical human epidermal growth factor receptor 2 (HER2)-negative breast cancer Information and one of the following A.) The patient is pre-or perimenopausal woman or male and the requested drug will be used as initial endocrine-based therapy, B.) The patient is postmenopausal, the requested drug will be used as initial endocrine-based therapy, and the patient has experienced disease progression, an intolerable adverse event, or contraindication to Ibrance (palbociclib) or Verzenio (abemaciclib) **Age Restrictions** 18 years of age and older Prescriber Prescribed by or in consultation with an oncologist Restrictions Coverage 12 months Duration **Other Criteria** None Indications All Medically-accepted Indications. **Off-Label Uses** N/A Part B No **Prerequisite**

KISQALI FEMARA (600 MG DOSE)

KORLYM

Products Affected

• KORLYM

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) pregnancy, B.) coadministration with simvastatin, lovastatin, or CYP3A substrates with narrow therapeutic ranges, C.) concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses, D.) history of unexplained vaginal bleeding, E.) endometrial hyperplasia with atypia or endometrial carcinoma |
| Required Medical Information | Diagnosis of endogenous Cushing syndrome in patients with type 2 diabetes mellitus or glucose intolerance and must meet all of the following 1.) Used to control hyperglycemia secondary to hypercortisolism, AND 2.) Patient has failed or is not a candidate for surgery |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

KOSELUGO

Products Affected

• KOSELUGO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of neurofibromatosis type 1 (NF1) in a patient who has symptomatic, inoperable plexiform neurofibromas (PN) |
| Age Restrictions | 2 years of age to 17 years of age |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

KRAZATI

Products Affected

• KRAZATI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of KRAS G12C-mutated locally advanced or metastatic non- small cell lung cancer (NSCLC) as determined by an FDA-approved test and patient has received at least one prior systemic therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LAPATINIB

Products Affected

• *lapatinib ditosylate*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced or metastatic breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND meets one of the following A.) Used in combination with capecitabine in a patient who has received prior therapy including an anthracycline, a taxane, and trastuzumab, OR B.) Used in combination with letrozole in a postmenopausal female for whom hormonal therapy is indicated |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LENALIDOMIDE

Products Affected

• *lenalidomide*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1- risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| 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 | None |
| Required Medical Information | Diagnosis of one of the following A.) Locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer, B.) Advanced renal cell carcinoma, in combination with everolimus, following one prior anti-angiogenic therapy, C.) Unresectable hepatocellular carcinoma, first-line therapy, D.) Advanced endometrial carcinoma that is not microsatellite instability-high or mismatch repair deficient, in combination with pembrolizumab, when disease has progressed following prior systemic therapy and patient is not a candidate for curative surgery or radiation, or E.) Advanced renal cell carcinoma, in combination with pembrolizumab and used as first-line therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LEUKINE

Products Affected

• LEUKINE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed, B.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, C.) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, D.) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, E.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) or F.) Autologous peripheral blood stem cell transplant, Following myeloablative chemotherapy. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LEUPROLIDE

Products Affected

| MG, 30 MG, 45 <i>leuprolide aceta</i> <i>leuprolide aceta</i> LUPRON DEPO | • LUPRON DEPOT-PED (1-MONTH) |
|--|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (7.5 mg 1-month, 22.5 mg 3-month, 30 mg |

| Exclusion Criteria | Pregnancy |
|------------------------------------|---|
| Required Medical Information | Must meet one of the following: 1.) Eligard only: Advanced or metastatic prostate cancer, or 2.) For Lupron depot and leuprolide products only: A.) Advanced or metastatic prostate cancer and patient has failed or is intolerant to Eligard or Trelstar (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), B.) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only), C.) Anemia due to uterine leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only), and patient is preoperative, or D.) Central precocious puberty (idiopathic or neurogenic) in children |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LIDOCAINE EXT

Products Affected

• lidocaine external ointment

• lidocaine hcl

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Amide hypersensitivity |
| Required Medical Information | The requested drug will be used for or topical anesthesia of skin or mucous membranes |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LINEZOLID

Products Affected

- *linezolid intravenous*
- linezolid oral suspension reconstituted

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Concomitant use of an MAOI, or B.) Use within 14 days of discontinuing an MAOI |
| Required Medical Information | Diagnosis of one of the following A.) Community acquired pneumonia, B.) Hospital-acquired pneumonia, C.) Vancomycin-resistant Enterococcus faecium infection, D.) Complicated skin and skin structure infections, or E.) Uncomplicated skin and skin structure infections |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 1 month |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• linezolid oral tablet

LONSURF

Products Affected

• LONSURF

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic colorectal cancer, previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based regimens, an anti-VEGF therapy, and if RAS wild-type, an anti-EGFR therapy, or B.) Metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least 2 prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan and if appropriate, HER2/neu-targeted therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LORBRENA

Products Affected

 LORBRENA ORAL TABLET 100 MG, 25 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Concomitant use with strong CYP3A4 inducers |
| Required Medical Information | Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non- small cell lung cancer (NSCLC) as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LUMAKRAS

Products Affected

 LUMAKRAS ORAL TABLET 120 MG, 320 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of KRAS G12C-mutated locally advanced or metastatic non- small cell lung cancer (NSCLC) as determined by an FDA-approved test, and patient has received at least one prior systemic therapy (e.g., immune checkpoint inhibitor, platinum-based chemotherapy) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | This criteria applies to new starts only |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

LYNPARZA

Products Affected

• LYNPARZA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) HER2-negative, deleterious or suspected deleterious germline BRCA mutated high-risk early or metastatic breast cancer AND patient has been previously treated with chemotherapy in neoadjuvant, adjuvant, or metastatic setting, B.) Recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer AND used for maintenance treatment in patients who are in complete or partial response to platinum-based chemotherapy (e.g. cisplatin, carboplatin), C.) Deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients with complete or partial response to first-line platinum-based chemotherapy, D.) Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma and disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen, E.) Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer in patients who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA-mutation and/or genomic instability AND are using in combination with bevacizumab for maintenance treatment, F.) Deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutated metastatic castration-resistant prostate cancer in patients who have progressed following prior treatment with enzalutamide or abiraterone, or G.) Deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer in combination with abiraterone and prednisone or prednisolone |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |

| PA Criteria | Criteria Details |
|------------------------|-------------------------------------|
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• LYTGOBI (12 MG DAILY DOSE)

• LYTGOBI (20 MG DAILY DOSE)

• LYTGOBI (16 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements and previously treated |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MATULANE

Products Affected

• MATULANE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Inadequate marrow reserve |
| Required Medical Information | Diagnosis of Hodgkin's Disease, Stages III and IV and used in combination with other anticancer drugs |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MAYZENT

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) CYP2C9*3/*3 genotype, B.) In the last 6 months experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III-IV heart failure, or C.) Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker |
| Required Medical Information | Diagnosis of one of the following A.) Relapsing forms of multiple sclerosis (e.g., clinically isolated syndrome, relapsing-remitting MS, active secondary progressive disease, or progressive-relapsing MS), or B.) Patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MEKINIST

Products Affected

• MEKINIST

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and used in combination with dabrafenib and no locoregional treatment options, B.) Malignant melanoma with lymph node involvement and following complete resection with BRAF V600E or V600K mutations and used in combination with dabrafenib, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutations and used in combination with dabrafenib or as monotherapy, D.) Metastatic non-small cell lung cancer, with BRAF V600E mutation, in combination with dabrafenib, E.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with dabrafenib, and have progressed following prior treatment and have no satisfactory alternative treatment options, F.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with dabrafenib |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MEKTOVI

Products Affected

• MEKTOVI

| PA Criteria | Criteria Details |
|------------------------------------|---|
| | |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Unresectable or metastatic malignant melanoma with documented BRAF V600E or V600K mutation as detected by an FDA approved test AND used in combination with encorafenib or B.) Metastatic non-small cell lung cancer with a BRAF V600E mutation as detected by an FDA-approved test AND used in combination with encorafenib |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

MIGLUSTAT

Products Affected

• miglustat

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of mild to moderate type 1 Gaucher disease and patient is not a candidate for enzyme replacement therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NAMZARIC

Products Affected

• NAMZARIC

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Hypersensitivity to memantine, donepezil, or excipients, or B.) Hypersensitivity to piperidine derivatives |
| Required Medical Information | Diagnosis of moderate to severe dementia associated with Alzheimer's disease |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NAYZILAM

Products Affected

• NAYZILAM

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Acute narrow angle glaucoma |
| Required Medical Information | Diagnosis of epilepsy and documentation of acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, acute repetitive seizures), that are distinct from a patient's usual seizure pattern |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | This criteria applies to new starts only |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NERLYNX

Products Affected

• NERLYNX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Early stage HER2-positive breast cancer and used following adjuvant trastuzumab therapy, or B.) Advanced or metastatic HER2-positive breast cancer, used in combination with capecitabine, AND patient has received 2 or more prior anti-HER2-based regimens in the metastatic setting |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NINLARO

Products Affected

• NINLARO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of multiple myeloma, used in combination with lenalidomide and dexamethasone, AND patient has history of at least 1 prior therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NUBEQA

Products Affected

• NUBEQA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Non-metastatic, castration-resistant prostate cancer (nmCRPC) or B.) Metastatic hormone-sensitive prostate cancer in combination with docetaxel. For treatment of nmCRPC, one of the following applies 1.) Used in combination with a gonadotropin- releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NUEDEXTA

Products Affected

• NUEDEXTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) History of prolonged QT interval, congenital long QT syndrome or Torsades de pointes, B.) Heart failure, C.) Complete AV block without an implanted pacemaker or high risk of complete AV block, D.) Concomitant use with quinidine, quinine, mefloquine, or drugs that prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), E.) Concomitant use with MAOIs or within 14 days of MAOI therapy, F.) History of quinine-, mefloquine-, or quinidine-induced thrombocytopenia, bone marrow depression, or lupus-like syndrome |
| Required Medical Information | Diagnosis of pseudobulbar affect |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

NUPLAZID

Products Affected

• NUPLAZID

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Parkinson's disease and both of the following apply A.) Used for treatment of hallucinations and/or delusions associated with Parkinson's disease psychosis, and B.) Diagnosis of Parkinson's disease was made prior to the onset of psychotic symptoms |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

OCTREOTIDE

Products Affected

• octreotide acetate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had inadequate response to or is ineligible for surgery, radiation, or bromocriptine mesylate, or B.) Metastatic carcinoid syndrome with associated diarrhea or flushing, or C.) Vasoactive intestinal peptide- secreting tumors (VIPomas) with associated diarrhea |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ODOMZO

Products Affected

• ODOMZO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of locally advanced basal cell carcinoma of the skin and one of the following A.) Cancer has recurred following surgery or radiation therapy, B.) Patient is not a candidate for surgery or radiation therapy. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• OFEV

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Idiopathic pulmonary fibrosis (IPF), B.) Systemic sclerosis-associated interstitial lung disease (ILD), or C.) Chronic fibrosing interstitial lung disease with a progressive phenotype |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

OGSIVEO

Products Affected

• OGSIVEO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of progressing desmoid tumors who require systemic treatment |
| Age Restrictions | 18 years or older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

OJJAARA

Products Affected

• OJJAARA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [postpolycythemia vera (PV) and post- essential thrombocythemia (ET)], in adults with anemia. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ONUREG

Products Affected

• ONUREG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of acute myeloid leukemia (AML) used in maintenance treatment for adult patients who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

OPSUMIT

Products Affected

• OPSUMIT

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e. g., patient is frail, elderly, etc.) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | Initial: 6 months, Renewal: Plan Year |
| Other Criteria | Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• ORENCIA CLICKJECT

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

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Moderate to severe polyarticular juvenile idiopathic arthritis, C.) Psoriatic arthritis, or D.) Prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in patients undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated-donor. Screening for latent tuberculosis infection is required prior to initiation of treatment. |
| Age Restrictions | None |
| Prescriber Restrictions | pJIA/PsA/RA: Prescribed by or in consultation with a dermatologist or rheumatologist. aGVHD: None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ORGOVYX

Products Affected

• ORGOVYX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced prostate cancer |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ORKAMBI

Products Affected

• ORKAMBI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis (CF) with documented homozygous F508del mutation confirmed by FDA-approved CF mutation test |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

ORSERDU ORAL TABLET 345 MG, 86
 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced or metastatic, ER-positive, HER2-negative, ESR1- mutated, breast cancer in postmenopausal women or adult man after at least 1 line of endocrine therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• OTEZLA ORAL TABLET

OTEZLA ORAL TABLET THERAPY PACK

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following: A.) Active psoriatic arthritis and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Cosentyx, Enbrel, Humira, Rinvoq, Skyrizi, Stelara), B.) Moderate to severe plaque psoriasis, patient is a candidate for phototherapy or systemic therapy, and patient has trial and failure or intolerance or contraindication to two preferred products, (i.e. Cosentyx, Enbrel, Humira, Skyrizi, Stelara), C.) Mild plaque psoriasis, patient is a candidate for phototherapy or systemic therapy, and patient has trial and failure or intolerance or contraindication to at least one topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analog), or D.) Behcet's Disease and patient has active oral ulcers |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | PsA: Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis: Prescribed by or in consultation with a dermatologist. |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PANRETIN

Products Affected

• PANRETIN

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of AIDS-related Kaposi's sarcoma and both of the following 1.) Used to treat cutaneous lesions, and 2.) Systemic anti-Kaposi's Sarcoma therapy is not indicated (e.g., patient does not have more than 10 new KS lesions in the prior month, symptomatic lymphedema, symptomatic pulmonary KS, or symptomatic visceral involvement) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or HIV specialist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PEGYLATED INTERFERON

Products Affected

• PEGASYS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Autoimmune hepatitis, B.) Hepatic decompensation (Child-Pugh score greater than 6 (Class B and C) in cirrhotic patients before treatment, OR hepatic decompensation (Child- Pugh score greater than or equal to 6) in cirrhotic patients co-infected with hepatitis C and HIV before treatment, C.) Hypersensitivity reactions, including urticaria, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome to alfa interferons or any component of the product, or D.) Pregnancy with concomitant ribavirin use |
| Required Medical Information | Diagnosis of one of the following A.) Chronic hepatitis B infection, or B.) Chronic hepatitis C and required criteria will be applied consistent with current AASLD-IDSA guidance with compensated liver disease |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PEMAZYRE

Products Affected

• PEMAZYRE

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with confirmed fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or B.) Relapsed or refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist, gastroenterologist, or hepatologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PENICILLAMINE

Products Affected

• penicillamine

| l | |
|------------------------------------|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Any of the following A.) Breastfeeding, B.) During Pregnancy (except for treatment of Wilson's disease), C.) Hypersensitivity to penicillamine products, D.) Penicillamine-related aplastic anemia/agranulocytosis, E.) Rheumatoid arthritis patients with history or evidence of renal insufficiency |
| Required Medical Information | Diagnosis of one of the following A.) Cystinuria, B.) Severe, active rheumatoid arthritis, or C.) Wilson's disease |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• PIQRAY (200 MG DAILY DOSE)

• PIQRAY (300 MG DAILY DOSE)

• PIQRAY (250 MG DAILY DOSE)

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hormone receptor (HR) positive, HER2-negative, PIK3CA- mutated, advanced or metastatic breast cancer and must meet all of the following 1.) Used in combination with fulvestrant, 2.) Disease has progressed on or after an endocrine-based regimen, and 3.) Patient is a male or postmenopausal female |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PIRFENIDONE

Products Affected

• pirfenidone

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of idiopathic pulmonary fibrosis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

POMALYST

Products Affected

• POMALYST

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) AIDS-related Kaposi sarcoma and patient has failure on highly active antiretroviral therapy (HAART), B.) Kaposi sarcoma in HIV-negative adults, or C.) Multiple myeloma and in combination with dexamethasone in adults who have received at least 2 prior therapies (including lenalidomide and a proteasome inhibitor) and have demonstrated disease progression on or within 60 days of completion of the last therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

POSACONAZOLE

Products Affected

- NOXAFIL
- posaconazole oral suspension

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Concomitant treatment with sirolimus, B.) Concomitant use of CYP3A4 substrates that prolong QT interval (pimozide, quinidine), C.) Concomitant use of HMG-CoA Reductase inhibitors primarily metabolized through CYP3A4, or D.) Concomitant use of ergot alkaloids |
| Required Medical Information | Diagnosis of one of the following A.) Oropharyngeal candidiasis, B.) Patient is severely immunocompromised and requires prophylaxis of invasive aspergillosis or candidiasis due to high risk of infection, or C.) Invasive aspergillosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 weeks |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• posaconazole oral tablet delayed release

PREVYMIS

Products Affected

• PREVYMIS

| DA Critoria | Critorio Dotoila |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Any of the following A.) Concomitant use with pimozide or ergot alkaloids (ergotamine, dihydroergotamine), B.) Concomitant use with pitavastatin or simvastatin when coadministered with cyclosporine |
| Required Medical Information | Diagnosis of one of the following A.) Prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, or B.) Prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PROLIA

Products Affected

• PROLIA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Hypocalcemia (calcium less than 8.0 mg/dL) |
| Required Medical Information | Must meet all of the following A.) Diagnosis of one of the following 1.) Treatment of osteoporosis in postmenopausal females at high risk of fracture, 2.) Treatment of osteoporosis in males at high risk of fracture 3.) Treatment of bone loss in males receiving androgen-deprivation therapy for nonmetastatic prostate cancer, 4.) Treatment of bone loss in females receiving aromatase inhibitor therapy for breast cancer, or 5.) Treatment of glucocorticoid-induced osteoporosis in patients at high risk of fracture who are initiating or continuing systemic glucocorticoids at a daily dose greater than or equal to 7.5 mg of prednisone for an anticipated duration of at least 6 months B.) Bone density scan (DEXA) documenting a T-score less than - 1.0 at lumbar spine, total hip, femoral neck, or 33% radius and member has high risk factors (high risk defined as osteoporotic fracture history, multiple risk factors for fracture, or failure of or intolerance to other available osteoporosis therapy) or T-score less than or equal to -2.5 in the lumbar spine, total hip, femoral neck, or 33% radius |
| Age Restrictions | none |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PROMACTA

Products Affected

PROMACTA ORAL PACKET 12.5 MG,
 PROMACTA ORAL TABLET 25 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic idiopathic thrombocytopenic purpura (ITP), B.) Chronic hepatitis C infection associated thrombocytopenia, or C.) Severe aplastic anemia with insufficient response to immunosuppressive therapy or in combination with standard immunosuppressive therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PULMOZYME

Products Affected

• PULMOZYME

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis (CF) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PURIXAN

Products Affected

• PURIXAN

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) Diagnosis of acute lymphocytic leukemia, 2.) Using in combination with methotrexate, 3.) Patient has tried/failed or has contraindication/intolerance to mercaptopurine tablets |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PYRIMETHAMINE

Products Affected

• pyrimethamine

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Documented megaloblastic anemia due to folate deficiency |
| Required Medical Information | Diagnosis of Toxoplasmosis and treatment in combination with a sulfonamide |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an infectious disease specialist |
| Coverage Duration | 10 weeks |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

QINLOCK

Products Affected

• QINLOCK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of advanced gastrointestinal stromal tumor (GIST) and patient has received prior treatment with 3 or more kinase inhibitors, including imatinib |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

QUININE SULFATE

Products Affected

• quinine sulfate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Prolongation of QT interval, B.) Glucose-6- phosphate dehydrogenase deficiency, C.) Myasthenia gravis, D.) Known hypersensitivity to mefloquine or quinidine, E.) Optic neuritis, F.) Diagnosis of Blackwater fever, G.) Use solely for treatment or prevention of nocturnal leg cramps |
| Required Medical Information | Diagnosis of one of the following A.) uncomplicated Plasmodium falciparum malaria, B.) uncomplicated Plasmodium vivax malaria, or C.) babesiosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 1 month |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RAVICTI

Products Affected

• RAVICTI

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of urea cycle disorders |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

REGRANEX

Products Affected

• REGRANEX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Known neoplasm at the site of application |
| Required Medical Information | Diagnosis of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply |
| Age Restrictions | 16 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

REPATHA

| Products Affected• REPATHA• REPATHA PUSHTRONEX SYSTEM• REPATHA SURECLICK | |
|--|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH), B.) homozygous familial hypercholesterolemia, C.) established cardiovascular disease and myocardial infarction prophylaxis, stroke prophylaxis, or coronary revascularization prophylaxis is required, or D.) clinical atherosclerotic cardiovascular disease (CVD) as defined as one of the following 1.) acute coronary syndrome, 2.) history of myocardial infarction, 3.) stable/unstable angina, 4.) coronary or other arterial revascularization, 5.) stroke, 6.) transient ischemic stroke (TIA), or 7.) peripheral arterial disease presumed to be atherosclerotic region |
| Age Restrictions | 10 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RETEVMO

Products Affected

RETEVMO ORAL CAPSULE 40 MG, 80
MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in patients who require systemic therapy, B.) Metastatic RET fusion-positive non-small cell lung cancer (NSCLC), C.) Advanced or metastatic RET fusion-positive thyroid cancer in patients who require systemic therapy and are refractory to radioactive iodine, if appropriate, or D.) Locally advanced or metastatic solid tumors with a RET gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

REVLIMID

Products Affected

• REVLIMID

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Multiple myeloma and medication will be used in combination with dexamethasone, B.) Autologous hematopoietic stem-cell transplantation (HSCT) in multiple myeloma patients, C.) Transfusion-dependent anemia due to low- or intermediate-1- risk myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality or without additional cytogenetic abnormalities, D.) Mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib, E.) Follicular lymphoma and used in combination with rituximab, or F.) Marginal zone lymphoma and used in combination with rituximab |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

REZLIDHIA

Products Affected

• REZLIDHIA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

REZUROCK

Products Affected

• REZUROCK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of chronic graft-vs-host disease and patient has failed at least 2 prior lines of systemic therapy. |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RILUZOLE

Products Affected

• riluzole

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of amyotrophic lateral sclerosis (ALS) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RINVOQ

Products Affected

• RINVOQ

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis, B.) Active psoriatic arthritis, C.) Moderate to severe atopic dermatitis and patient has trial/failure, contraindication, or intolerance to two of the following 1.) Topical corticosteroid and/or 2.) Topical calcineurin inhibitor, D.) Moderately to severely active ulcerative colitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers, E.) Active ankylosing spondylitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers, F.) Active nonradiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to tumor necrosis factor blocker therapy, or G.) Moderate to severe active Crohn's disease who have had an inadequate response or intolerance to tumor necrosis factor blocker therapy |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ROZLYTREK

Products Affected

ROZLYTREK ORAL CAPSULE 100
 MG, 200 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) ROS1-positive metastatic non-small cell lung cancer (NSCLC), or B.) Solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have either progressed following treatment or have no satisfactory alternative therapy |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | Verify the pregnancy status of females of reproductive potential prior to initiating ROZLYTREK |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RUBRACA

Products Affected

• RUBRACA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, used as maintenance treatment, and patient is in complete or partial response to platinum-based chemotherapy, or B.) Deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer and patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RUFINAMIDE

Products Affected

• rufinamide oral suspension

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Familial Short QT Syndrome |
| Required Medical Information | Diagnosis of seizures associated with Lennox-Gastaut syndrome and used as adjunctive treatment |
| Age Restrictions | 1 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

RYDAPT

Products Affected

• RYDAPT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) treatment naive FLT3 mutation- positive acute myelogenous leukemia (AML) and must be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation therapy, or B.) systemic mastocytosis or mast cell leukemia |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SAPROPTERIN

Products Affected

• sapropterin dihydrochloride

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hyperphenylalaninemia (HPA) caused by tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Initial: 2 months, Renewal: Plan year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SCEMBLIX

Products Affected

• SCEMBLIX

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), or B.) Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SIGNIFOR

Products Affected

• SIGNIFOR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Cushing disease and patient has had inadequate response to or is not a candidate for surgery. For renewal: Documentation of a clinically meaningful reduction in 24-hour urinary free cortisol (UFC) levels or improvement in signs or symptoms of the disease |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SILDENAFIL

Products Affected

• sildenafil citrate oral tablet 20 mg

| | T |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Any of the following A.) Nitrate therapy, including intermittent use, B.) Concomitant use with riocguat or other guanylate cyclase stimulators, C.) Concomitant use with HIV protease inhibitors or elvitegravir/cobicistat/tenofovir/emtricitabine |
| Required Medical Information | Diagnosis of pulmonary arterial hypertension (WHO Group I), confirmed by right heart catheterization or Doppler echocardiogram if patient is unable to undergo a right heart catheterization (e.g., patient is frail, elderly, etc.) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist or pulmonologist |
| Coverage Duration | 12 months |
| Other Criteria | Continuation of therapy: patient is tolerating and responding to medication and has improved exercise capacity or a delay in clinical worsening. |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SIRTURO

Products Affected

• SIRTURO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Must meet all of the following 1.) Diagnosis of pulmonary multidrug resistant tuberculosis (MDR-TB) and 2.) Used in combination with at least 3 other antibiotics for the treatment of pulmonary multi-drug resistant tuberculosis |
| Age Restrictions | 5 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an infectious disease specialist |
| Coverage Duration | 24 weeks |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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 | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe plaque psoriasis and patient is a candidate for systemic therapy or phototherapy, B.) Active psoriatic arthritis, or C.) Moderately to severely active Crohn's disease. Screening for latent tuberculosis infection is required prior to initiation of treatment. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a dermatologist, gastroenterologist, or rheumatologist |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SODIUM OXYBATE

Products Affected

• sodium oxybate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Concomitant treatment with sedative hypnotic agents, B.) Succinic semialdehyde dehydrogenase deficiency |
| Required Medical Information | Diagnosis of one of the following A.) Narcolepsy with excessive daytime drowsiness and has trial of/or contraindication to a central nervous system (CNS) stimulant drug (e.g., amphetamine, dextroamphetamine, methylphenidate) or a CNS wakefulness promoting drug (e.g., armodafinil, modafinil), or B.) Cataplexy and narcolepsy |
| Age Restrictions | 7 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• SOHONOS ORAL CAPSULE 1 MG, 1.5 MG, 10 MG, 2.5 MG, 5 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of fibrodysplasia ossificans progressiva (FOP) |
| Age Restrictions | 8 years and older for females and 10 years and older for males |
| Prescriber Restrictions | None |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SOLTAMOX

Products Affected

• SOLTAMOX

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Concomitant coumarin-type anticoagulant therapy, B.) history of thromboembolic disease such as DVT or PE |
| Required Medical Information | Diagnosis of breast cancer and documentation of inability to swallow tablet formulation |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• SOMAVERT SUBCUTANEOUS SOLUTION RECONSTITUTED 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of acromegaly confirmed by high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range and patient has had an inadequate response to or is ineligible for surgery or radiation therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an endocrinologist |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SORAFENIB

Products Affected

• sorafenib tosylate

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Squamous cell lung cancer being treated with carboplatin and paclitaxel |
| Required Medical Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, B.) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma that is refractory to radioactive iodine treatment, or C.) Unresectable hepatocellular carcinoma |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, B.) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy, C.) Ph+ acute lymphoblastic leukemia (ALL) with resistance or intolerance to prior therapy, or D.) Newly diagnosed Ph+ ALL in combination with chemotherapy |
| Age Restrictions | 1 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

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

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severely active Crohn's disease, B.) Moderate to severe plaque psoriasis, C.) Active psoriatic arthritis, or D.) Moderate to severe active ulcerative colitis. Screening for latent tuberculosis infection is required prior to initiation of treatment. |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a dermatologist, rheumatologist, or gastroenterologist |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

STIVARGA

Products Affected

• STIVARGA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic colorectal cancer in patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan containing chemotherapy, anti-VEGF therapy, and if RAS wild type, anti-EGFR therapy, B.) Liver carcinoma in patients previously treated with sorafenib, or C.) Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) after treatment with imatinib and sunitinib |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SUNITINIB

Products Affected

• *sunitinib malate*

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Gastrointestinal stromal tumor after disease progression on or intolerance to imatinib, B.) Pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, C.) Advanced renal cell carcinoma, or D.) Renal cell carcinoma and used as adjuvant therapy following nephrectomy in patients who are at high risk for recurrence |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• SYMLINPEN 120

• SYMLINPEN 60

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Confirmed diagnosis of gastroparesis, B.) Hypoglycemia unawareness |
| Required Medical Information | Diagnosis of type 1 or type 2 diabetes mellitus and patient uses mealtime insulin therapy and has failed to achieve desired glucose control |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

SYNAREL

Products Affected

• SYNAREL

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) pregnancy, B.) breastfeeding, C.) undiagnosed abnormal vaginal bleeding |
| Required Medical Information | Diagnosis of one of the following A.) Central precocious puberty, or B.) Endometriosis |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TABRECTA

Products Affected

• TABRECTA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) in patients whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TADALAFIL

Products Affected

• tadalafil

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) concurrent use of nitrates, including intermittent use, or B.) diagnosis of erectile dysfunction without signs and symptoms of BPH |
| Required Medical Information | Diagnosis of benign prostatic hyperplasia (BPH) and patient has experienced intolerance to or treatment failure to ONE alpha-blocker (e.g., doxazosin, prazosin, tamsulosin) AND to ONE 5-alpha reductase inhibitor (e.g., dutasteride, finasteride). |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TAFINLAR

Products Affected

• TAFINLAR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Locally advanced or metastatic anaplastic thyroid carcinoma with BRAF V600E mutation, in combination with trametinib and no satisfactory locoregional treatment options, B.) Metastatic non-small cell lung cancer with BRAF V600E mutation, in combination with trametinib OR in patients previously treated as monotherapy, C.) Unresectable or metastatic malignant melanoma with BRAF V600E or V600K mutation, D.) Unresectable or metastatic solid tumors with BRAF V600E mutation, in combination with trametinib, and have progressed following prior treatment and have no satisfactory alternative treatment options, or E.) Low-grade glioma with a BRAF V600E mutation and require systemic therapy, in combination with trametinib |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TAGRISSO

Products Affected

• TAGRISSO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) with EGFR exon 19 deletion or exon 21 L858R mutation and used as first line therapy, B.) Metastatic non-small cell lung cancer with T790M EGFR mutation (as confirmed by an FDA-approved test) AND whose disease has progressed on or after EGFR tyrosine kinase inhibitor therapy, or C.) Non-small cell lung cancer (NSCLC) with tumor epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations (as confirmed by an FDA-approved test) AND patient requires adjuvant therapy after tumor resection |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TALZENNA

Products Affected

• TALZENNA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, or B.) Homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer in combination with enzulatamide |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TASIGNA

Products Affected

• TASIGNA

| | T |
|------------------------------------|--|
| PA Criteria | Criteria Details |
| Exclusion Criteria | Any of the following A.) Long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia |
| Required Medical Information | Diagnosis of one of the following A.) Newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia (CML), B.) Chronic phase or accelerated phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior therapy that included imatinib, or C.) Chronic phase Philadelphia chromosome-positive CML in a patient with resistance or intolerance to prior tyrosine-kinase inhibitor therapy |
| Age Restrictions | 1 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TAZAROTENE

Products Affected

• tazarotene external cream

• TAZORAC

• tazarotene external gel

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Acne vulgaris and patient has trial with at least one generic topical acne product, or B.) Stable moderate to severe plaque psoriasis with 20% or less body surface area involvement and patient has trial with at least one other topical psoriasis product (e.g., medium to high potency corticosteroid and/or vitamin D analogs) |
| Age Restrictions | 12 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TAZVERIK

Products Affected

• TAZVERIK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic or locally advanced epithelioid sarcoma in patients not eligible for complete resection, B.) Relapsed or refractory follicular lymphoma in patients whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, or C.) Relapsed or refractory follicular lymphoma in patients who have no satisfactory alternative treatment options |
| Age Restrictions | 16 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ТЕРМЕТКО

Products Affected

• TEPMETKO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic non-small cell lung cancer (NSCLC) with mesenchymal-epithelial transition (MET) exon 14 skipping alterations |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TERIPARATIDE

Products Affected

• *teriparatide (recombinant)*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Osteoporosis in postmenopausal female patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate or Tymlos, B.) Primary or hypogonadal osteoporosis in male patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate, or C.) Osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate, or C.) Osteoporosis due to associated sustained systemic glucocorticoid therapy in patient with high risk for fracture and patient has contraindication or has tried/had inadequate response to a bisphosphonate |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year (Maximum 24 month treatment per patient lifetime) |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TETRABENAZINE

Products Affected

• *tetrabenazine oral tablet 12.5 mg, 25 mg*

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Any of the following A.) Actively suicidal, B.) Untreated or inadequately treated depression, C.) Impaired hepatic function, D.) Concomitant use of monoamine oxidase inhibitors, E.) Concomitant use of reserpine or within 20 days of discontinuing reserpine |
| Required Medical Information | Diagnosis of chorea associated with Huntington's disease |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

THALOMID

Products Affected

• THALOMID

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Multiple myeloma that is newly diagnosed, or B.) Erythema nodosum leprosum (ENL) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist, infectious disease specialist, or dermatologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TIBSOVO

Products Affected

• TIBSOVO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test), B.) Previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test.), C.) Acute myeloid leukemia (newly-diagnosed) with susceptible isocitrate dehydrogenase-1 mutation and meets one of the following: 1.) Patient is 75 years of age or older, or 2.) Patient has comorbidities that preclude intensive induction chemotherapy, or D.) Relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation (as detected by an FDA-approved test) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a gastroenterologist, hematologist, hepatologist, or oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

• TOBI PODHALER

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Known sensitivity to any aminoglycoside |
| Required Medical Information | Diagnosis of cystic fibrosis (confirmed by appropriate diagnostic or genetic testing) and patient has suspected or confirmed Pseudomonas aeruginosa infection in the lungs |
| Age Restrictions | 6 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TOPICAL RETINOIDS

Products Affected

• adapalene

• tretinoin external

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of mild to moderate acne vulgaris |
| Age Restrictions | PA applies to patients older than 26 years of age |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TOPICAL TESTOSTERONE

Products Affected

PA Criteria

Exclusion

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

Criteria Details Any of the following A.) Carcinoma of the breast (males only), B.) Known or suspected carcinoma of the prostate, C.) Pregnancy

| Criteria | or suspected carcinoma of the prostate, C.) Pregnancy |
|------------------------------------|---|
| Required Medical Information | Diagnosis of one of the following A.) Hypogonadotropic hypogonadism, or B.) Primary hypogonadism. Diagnosis of hypogonadism must be confirmed by a low-for-age serum testosterone (total or free) level defined by the normal laboratory reference value |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TOREMIFENE

Products Affected

• toremifene citrate

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Acquired or congenital long QT syndrome, B.) Uncorrected hypokalemia, C.) Uncorrected hypomagnesemia |
| Required Medical Information | Diagnosis of metastatic breast cancer and patient must have previous inadequate response or intolerance to tamoxifen |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

Products Affected

TRELSTAR MIXJECT
 INTRAMUSCULAR SUSPENSION

RECONSTITUTED 11.25 MG, 22.5 MG, 3.75 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of advanced prostate cancer |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TRIENTINE

Products Affected

• trientine hcl

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Wilson's disease in patients that are intolerant to penicillamine |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TRIKAFTA

Products Affected

• TRIKAFTA ORAL TABLET THERAPY • PACK

TRIKAFTA ORAL THERAPY PACK 100-50-75 & 75 MG, 80-40-60 & 59.5 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cystic fibrosis (CF) and patient has at least 1 F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to elexacaftor/tezacaftor/ivacaftor verified by an FDA-cleared CF mutation test |
| Age Restrictions | 2 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a pulmonologist or prescribing practitioner is from a CF center accredited by the Cystic Fibrosis Foundation |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TRUQAP

Products Affected

• TRUQAP

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer with 1 or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test and, A.) patient has had disease progression following 1 or more endocrine-based regimen(s) in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy, and B.) will be used in combination with fulvestrant injection. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TUKYSA

Products Affected

• TUKYSA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following: A.) advanced unresectable or metastatic HER2-positive breast cancer (including brain metastases) in patients who have received one or more prior anti-HER2-based regimens in the metastatic setting and drug is being used in combination with trastuzumab and capecitabine, or B.) unresectable or metastatic RAS wild-type, HER2-positive colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy and drug is being used in combination with trastuzumab |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TURALIO

Products Affected

• TURALIO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery. Liver function tests prior to initiation. |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

TYMLOS

Products Affected

• TYMLOS

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of osteoporosis in men or postmenopausal women and one of the following A.) osteoporotic fracture or multiple risk factors for fracture, or B.) previous trial of/or contraindication to bisphosphonate |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year (Maximum 24 month treatment per patient lifetime) |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

UBRELVY

Products Affected

• UBRELVY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin) |
| Required Medical Information | Diagnosis of migraine disorder with or without aura and patient has documented trial, inadequate response, or contraindication to at least 1 generic formulary triptan |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VALCHLOR

Products Affected

• VALCHLOR

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of cutaneous T-cell lymphoma (stage IA and IB mycosis fungoides-type) and patient has received prior skin-directed therapy (e.g. Topical corticosteroids, phototherapy, or topical nitrogen mustard) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VANFLYTA

Products Affected

• VANFLYTA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Patient must have all of the following A.) Newly diagnosed acute myeloid leukemia with FLT3-ITD mutation, B.) Used in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, and C.) Must be enrolled in the VANFLYTA REMS program |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VENCLEXTA

Products Affected

• VENCLEXTA

• VENCLEXTA STARTING PACK

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Concomitant use with strong CYP3A inhibitor during the initial and titration phase in patients with CLL or SLL |
| Required Medical Information | Diagnosis of one of the following A.) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), or B.) Newly-diagnosed acute myeloid leukemia (AML) and used in combination with azacitidine, decitabine or low-dose cytarabine in patients 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VERQUVO

Products Affected

• VERQUVO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| ТАСПина | |
| Exclusion Criteria | Any of the following A.) Concomitant use of other soluble guanylate cyclase (sGC) stimulators, or B.) Pregnancy |
| Required Medical Information | Diagnosis of chronic heart failure (HF), NYHA Class II to IV and all of the following 1.) Left ventricular ejection fraction less than 45%, 2.) Previous hospitalization for HF within 6 months or outpatient IV diuretic treatment for HF within 3 months |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a cardiologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VERZENIO

Products Affected

• VERZENIO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer and ALL of the following: 1.) Patient is at high risk of recurrence, and 2.) Requested drug will be used in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment, OR B.) Advanced or metastatic, hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative breast cancer and one of the following 1.) Used in combination with fulvestrant in a patient with disease progression following endocrine therapy, 2.) Used as monotherapy in a patient with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting, or 3.) For postmenopausal women, and men, used as initial endocrine-based treatment in combination with an aromatase inhibitor |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VIGABATRIN

Products Affected

- vigabatrin
- VIGADRONE

| • VIGADRONE | |
|------------------------------------|---|
| PA Criteria | Criteria Details |
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Infantile spasms, or B.) Refractory complex partial seizures and the drug is being used as adjunctive therapy in patients who have responded inadequately to two alternative treatments |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• VIGPODER

VIJOICE

Products Affected

• VIJOICE

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) in patients who require systemic therapy |
| Age Restrictions | 2 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VITRAKVI

Products Affected

VITRAKVI ORAL CAPSULE 100 MG,
 VITRAKVI ORAL SOLUTION 25 MG

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic or surgically unresectable neurotrophic receptor tyrosine kinase (NTRK) gene fusion positive solid tumors without a known acquired resistance mutation and used in patients with unsatisfactory alternative treatments or who have progressed following treatment |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VIZIMPRO

Products Affected

• VIZIMPRO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic non-small cell lung cancer with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• VONJO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of intermediate or high-risk primary or secondary myelofibrosis in adults AND a platelet count less than 50 X 10(9)/L |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

VORICONAZOLE

Products Affected

- voriconazole intravenous
- voriconazole oral suspension reconstituted

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | Any of the following A.) Concomitant use of carbamazepine, CYP3A4 substrates (e.g., terfenadine, astemizole, cisapride, pimozide, or quinidine), B.) Concomitant use with high-dose ritonavir (400mg every 12 hours), C.) Concomitant use with ergot alkaloids, D.) Concomitant use with long- acting barbiturates, E.) ConcOmitant use with rifabutin or rifampin, F.) Concomitant use with sirolimus, or G.) Concomitant use with efavirenz at standard doses of 400mg/day or higher |
| Required Medical Information | Diagnosis of one of the following A.) Invasive aspergillosis, B.) Candidemia, C.) Esophageal Candidiasis, D.) Invasive candidiasis of the skin and abdomen, kidney, bladder wall, and wounds, or E.) Serious fungal infection due to Scedosporium apiospermum or Fusarium species |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an infectious disease specialist |
| Coverage Duration | 6 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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voriconazole oral tablet 200 mg, 50 mg

VOTRIENT

Products Affected

• VOTRIENT

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Advanced renal cell carcinoma, or B.) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

WELIREG

Products Affected

• WELIREG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Pregnancy |
| Required Medical Information | Diagnosis of one of the following A.) Von Hippel-Lindau (VHL) disease and therapy is required for any of the following disease associated tumors that do not require immediate surgery 1.) Renal cell carcinoma (RCC), 2.) Central nervous system (CNS) hemangioblastoma, or 3.) Pancreatic neuroendocrine tumor (pNET), or B.) Advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• XALKORI ORAL CAPSULE

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

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive or ROS1- positive as detected by an FDA-approved test, B.) Relapsed or refractory systemic anaplastic large cell lymphoma that is anaplastic lymphoma kinase (ALK) positive as detected by an FDA-approved test, or C.) Unresectable, recurrent, or refractory inflammatory myofibroblastic tumors that are anaplastic lymphoma kinase (ALK)-positive |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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Products Affected

- XCOPRI (250 MG DAILY DOSE)
- XCOPRI ORAL TABLET THERAPY PACK
- XCOPRI (350 MG DAILY DOSE) XCOPRI ORAL TABLET 100 MG, 150 • MG, 200 MG, 50 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Familial short QT syndrome |
| Required Medical Information | Diagnosis of partial-onset seizures |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XDEMVY

Products Affected

• XDEMVY

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Demodex blepharitis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• XELJANZ ORAL SOLUTION

• XELJANZ XR

• XELJANZ ORAL TABLET 10 MG, 5 MG

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| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Moderate to severe rheumatoid arthritis (RA), B.) Active psoriatic arthritis, C.) Moderate to severe ulcerative colitis (UC), D.) Polyarticular course juvenile idiopathic arthritis (pcJIA), or E.) Active ankylosing spondylitis. Screening for latent tuberculosis infection is required prior to initiation of treatment. |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | Screening for latent tuberculosis infection is required prior to initiation of treatment |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XERMELO

Products Affected

• XERMELO

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of carcinoid syndrome diarrhea and both of the following 1.) Diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide, lanreotide) for at least 3 months, and 2.) Used in combination with SSA therapy |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist |
| Coverage Duration | Plan year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• XGEVA

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | Hypocalcemia (calcium less than 8.0 mg/dL) |
| Required Medical Information | Diagnosis of one of the following A.) Bone metastases from a solid tumor, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, B.) Multiple myeloma, used for the prevention of skeletal related events and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, C.) Hypercalcemia of malignancy refractory to bisphosphonate therapy and must have an inadequate treatment response, adverse event, or contraindication to zoledronic acid, or D.) Giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | B vs D determination required per CMS guidance |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | Yes |

XOLAIR

Products Affected

• XOLAIR

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chronic idiopathic urticaria in patients who remain symptomatic despite H1 antihistamine therapy, B.) Moderate to severe persistent asthma in patients with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms are inadequately controlled with inhaled corticosteroids or Dupixent, or C.) Nasal polyps in patients with inadequate response to nasal corticosteroids |
| Age Restrictions | 6 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, or pulmonologist |
| Coverage Duration | Initial: 6 months, Renewal: Plan Year |
| Other Criteria | B vs D coverage determination per CMS guidelines |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

XOSPATA

Products Affected

• XOSPATA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an Oncologist or Hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

- XPOVIO (100 MG ONCE WEEKLY)
- XPOVIO (40 MG ONCE WEEKLY)
- XPOVIO (40 MG TWICE WEEKLY)
- XPOVIO (60 MG ONCE WEEKLY)

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Relapsed or refractory multiple myeloma being used in combination with dexamethasone in a patient who has received at least 4 prior therapies and is refractory to at least 2 proteasome inhibitors, at least 2 immunomodulatory agents, and an anti- CD38 monoclonal antibody, B.) Multiple myeloma being used in combination with bortezomib and dexamethasone in a patient who has received at least 1 prior therapy, C.) Relapsed or refractory diffuse large B- cell lymphoma not otherwise specified, or D.) Relapsed or refractory DLBCL arising from follicular lymphoma and patient has received at least 2 lines of systemic therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• XPOVIO (60 MG TWICE WEEKLY)

• XPOVIO (80 MG ONCE WEEKLY)

• XPOVIO (80 MG TWICE WEEKLY)

XTANDI

Products Affected

• XTANDI

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Castration-resistant prostate cancer (CRPC), B.) Metastatic, castration-sensitive prostate cancer (mCSPC). For treatment of CRPC and mCSPC, one of the following applies 1.) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy, or C.) Nonmetastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• YONSA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of metastatic, castration-resistant prostate cancer (mCRPC) and used in combination with methylprednisolone. For treatment of mCRPC, one of the following applies: 1.) Used in combination with a gonadotropin- releasing hormone (GnRH) analog or 2) Patient has received bilateral orchiectomy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or urologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZARXIO

Products Affected

• ZARXIO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Chemotherapy induced febrile neutropenia (prophylaxis), B.) Severe chronic neutropenia, C.) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or D.) Hematopoietic subsyndrome of acute radiation syndrome (H-ARS) |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZEJULA

Products Affected

• ZEJULA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of Advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and used as maintenance therapy in a patient who is in a complete or partial response to platinum-based chemotherapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZELBORAF

Products Affected

• ZELBORAF

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Unresectable or metastatic melanoma and patient has positive BRAF-V600E mutation documented by an FDA- approved test, or B.) Erdheim-Chester disease and patient has documented BRAF V600 mutation |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZIEXTENZO

Products Affected

ZIEXTENZO

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of a non-myeloid malignancy and drug is being used as prophylaxis for chemotherapy-induced neutropenia |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | Plan Year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

• ZILBRYSQ SUBCUTANEOUS SOLUTION PREFILLED SYRINGE 23 MG/0.574ML, 32.4 MG/0.81ML

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of generalized myasthenia gravis in adults who are anti- acetylcholine receptor (AChR) antibody positive |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | Plan year |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZOKINVY

Products Affected

• ZOKINVY

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of one of the following A.) Hutchinson-Gilford Progeria Syndrome, or B.)Processing deficient progeroid laminopathy with documentation of either heterozygous LMNA mutation with progerin-like protein accumulation or homozygous or compound heterozygous ZMPSTE24 mutations |
| Age Restrictions | None |
| Prescriber Restrictions | None |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZOLINZA

Products Affected

• ZOLINZA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of primary cutaneous T-cell lymphoma (CTCL) in patients who have progressive, persistent or recurrent disease on or following two systemic therapies (e.g., bexarotene, romidepsin, etc) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZTALMY

Products Affected

• ZTALMY

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) |
| Age Restrictions | None |
| Prescriber Restrictions | Prescribed by or in consultation with a neurologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

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

| PA Criteria | Criteria Details |
|------------------------------------|-------------------------------------|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of postpartum depression |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | None |
| Coverage Duration | 14 days |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZYDELIG

Products Affected

ZYDELIG ORAL TABLET 100 MG, 150 MG

| PA Criteria | Criteria Details |
|------------------------------------|---|
| Exclusion Criteria | History of toxic epidermal necrosis with any drug |
| Required Medical Information | Diagnosis of Chronic lymphocytic leukemia, used in combination with rituximab and patient has relapsed on at least one prior therapy |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist or hematologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

ZYKADIA

Products Affected

• ZYKADIA

| PA Criteria | Criteria Details |
|------------------------------------|--|
| Exclusion Criteria | None |
| Required Medical Information | Diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non- small cell lung cancer (NSCLC) |
| Age Restrictions | 18 years of age and older |
| Prescriber Restrictions | Prescribed by or in consultation with an oncologist |
| Coverage Duration | 12 months |
| Other Criteria | None |
| Indications | All Medically-accepted Indications. |
| Off-Label Uses | N/A |
| Part B Prerequisite | No |

PART B VERSUS PART D

Products Affected

- acetylcysteine inhalation solution 10 %, 20 %
- acyclovir sodium intravenous solution 50 mg/ml
- albuterol sulfate inhalation nebulization solution (2.5 mg/3ml) 0.083%, 0.63 mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml
- amphotericin b intravenous solution reconstituted 50 mg
- amphotericin b liposome intravenous suspension reconstituted 50 mg
- ampicillin sodium injection solution reconstituted 1 gm, 125 mg
- aprepitant oral capsule 125 mg, 40 mg, 80 & 125 mg, 80 mg
- azathioprine oral tablet 50 mg
- azithromycin intravenous solution reconstituted 500 mg
- budesonide inhalation suspension 0.25 mg/2ml, 0.5 mg/2ml, 1 mg/2ml
- calcitonin (salmon) nasal solution 200 unit/act
- calcitriol oral capsule 0.25 mcg, 0.5 mcg
- calcitriol oral solution 1 mcg/ml
- cefoxitin sodium intravenous solution reconstituted 1 gm, 10 gm, 2 gm
- *cefuroxime sodium injection solution reconstituted 750 mg*
- cefuroxime sodium intravenous solution reconstituted 1.5 gm
- cinacalcet hcl oral tablet 30 mg, 60 mg, 90 mg
- CINRYZE INTRAVENOUS SOLUTION RECONSTITUTED 500 UNIT
- ciprofloxacin in d5w intravenous solution 200 mg/100ml
- clindamycin phosphate injection solution 600 mg/4ml, 900 mg/6ml
- CLINIMIX/DEXTROSE (4.25/5)
 INTRAVENOUS SOLUTION 4.25 %

Prior Authorization Criteria

CLINIMIX/DEXTROSE (5/15) INTRAVENOUS SOLUTION 5 %

- CLINIMIX/DEXTROSE (5/20)
 INTRAVENOUS SOLUTION 5 %
- colistimethate sodium (cba) injection solution reconstituted 150 mg
- cromolyn sodium inhalation nebulization solution 20 mg/2ml
- cyclophosphamide oral capsule 25 mg, 50 mg
- cyclophosphamide oral tablet 25 mg, 50 mg
- cyclosporine modified oral capsule 100 mg, 25 mg, 50 mg
- cyclosporine modified oral solution 100 mg/ml
- cyclosporine oral capsule 100 mg, 25 mg
- dextrose intravenous solution 10 %, 5 %
- dextrose-nacl intravenous solution 10-0.2 %, 10-0.45 %, 2.5-0.45 %
- DOXY 100 INTRAVENOUS SOLUTION RECONSTITUTED 100 MG
- ENGERIX-B INJECTION SUSPENSION
 20 MCG/ML
- ENGERIX-B INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/0.5ML, 20 MCG/ML
- ENVARSUS XR ORAL TABLET EXTENDED RELEASE 24 HOUR 0.75 MG, 1 MG, 4 MG
- everolimus oral tablet 0.25 mg, 0.5 mg, 0.75 mg, 1 mg
- fluconazole in sodium chloride intravenous solution 200-0.9 mg/100ml-%, 400-0.9 mg/200ml-%
- GAMMAGARD INJECTION SOLUTION 2.5 GM/25ML
- GAMMAGARD S/D LESS IGA INTRAVENOUS SOLUTION RECONSTITUTED 10 GM, 5 GM

- GAMMAPLEX INTRAVENOUS
 SOLUTION 10 GM/100ML, 10 GM/200ML, 20 GM/200ML, 5 GM/50ML
- GAMUNEX-C INJECTION SOLUTION
 1 GM/10ML
- granisetron hcl oral tablet 1 mg
- heparin sodium (porcine) injection solution 10000 unit/ml, 20000 unit/ml, 5000 unit/ml
- HEPLISAV-B INTRAMUSCULAR SOLUTION PREFILLED SYRINGE 20 MCG/0.5ML
- IMOVAX RABIES INTRAMUSCULAR SUSPENSION RECONSTITUTED 2.5 UNIT/ML
- ipratropium bromide inhalation solution 0.02 %
- *ipratropium-albuterol inhalation solution* 0.5-2.5 (3) mg/3ml
- ISOLYTE-P IN D5W INTRAVENOUS
 SOLUTION
- ISOLYTE-S PH 7.4 INTRAVENOUS SOLUTION
- kcl in dextrose-nacl intravenous solution 10-5-0.45 meq/l-%-%, 20-5-0.2 meq/l-%-%, 20-5-0.45 meq/l-%-%, 20-5-0.9 meq/l-%-%, 30-5-0.45 meq/l-%-%, 40-5-0.45 meq/l-%-%, 40-5-0.9 meq/l-%-%
- *kcl-lactated ringers-d5w intravenous solution 20 meq/l*
- levalbuterol hcl inhalation nebulization solution 0.31 mg/3ml, 0.63 mg/3ml, 1.25 mg/0.5ml, 1.25 mg/3ml
- *methotrexate sodium (pf) injection solution 50 mg/2ml*
- *methotrexate sodium injection solution 50 mg/2ml*
- *metronidazole intravenous solution 500 mg/100ml*
- *multiple electro type 1 ph 5.5 intravenous solution*
- mycophenolate mofetil oral capsule 250 mg

- mycophenolate mofetil oral suspension reconstituted 200 mg/ml
- mycophenolate mofetil oral tablet 500 mg
- mycophenolate sodium oral tablet delayed release 180 mg, 360 mg
- NUTRILIPID INTRAVENOUS EMULSION 20 %
- ondansetron hcl oral solution 4 mg/5ml
- ondansetron hcl oral tablet 4 mg, 8 mg
- ondansetron oral tablet dispersible 4 mg, 8 mg
- paricalcitol oral capsule 1 mcg, 2 mcg, 4 mcg
- penicillin g potassium injection solution reconstituted 20000000 unit
- penicillin g sodium injection solution reconstituted 5000000 unit
- pentamidine isethionate inhalation solution reconstituted 300 mg
- pentamidine isethionate injection solution reconstituted 300 mg
- PLASMA-LYTE A INTRAVENOUS
 SOLUTION
- potassium chloride in nacl intravenous solution 20-0.45 meq/l-%, 20-0.9 meq/l-%, 40-0.9 meq/l-%
- potassium chloride intravenous solution 10 meq/100ml, 2 meq/ml, 2 meq/ml (20 ml), 20 meq/100ml, 40 meq/100ml
- potassium cl in dextrose 5% intravenous solution 20 meq/l
- PREHEVBRIO INTRAMUSCULAR SUSPENSION 10 MCG/ML
- PROGRAF ORAL PACKET 0.2 MG, 1
 MG
- RABAVERT INTRAMUSCULAR SUSPENSION RECONSTITUTED
- RECOMBIVAX HB INJECTION SUSPENSION 10 MCG/ML, 40 MCG/ML, 5 MCG/0.5ML
- RECOMBIVAX HB INJECTION SUSPENSION PREFILLED SYRINGE 10 MCG/ML, 5 MCG/0.5ML

- SANDIMMUNE ORAL SOLUTION 100 MG/ML
- sirolimus oral solution 1 mg/ml
- sirolimus oral tablet 0.5 mg, 1 mg, 2 mg
- tacrolimus oral capsule 0.5 mg, 1 mg, 5 mg
- TEFLARO INTRAVENOUS SOLUTION RECONSTITUTED 400 MG, 600 MG
- tigecycline intravenous solution reconstituted 50 mg
- tobramycin inhalation nebulization solution 300 mg/5ml

- *tobramycin sulfate injection solution 10 mg/ml, 80 mg/2ml*
- TPN ELECTROLYTES INTRAVENOUS CONCENTRATE
- TRAVASOL INTRAVENOUS SOLUTION 10 %
- TROPHAMINE INTRAVENOUS SOLUTION 10 %
- XATMEP ORAL SOLUTION 2.5 MG/ML

Details

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

Alphabetical Listing

A

| ABILIFY ASIMTUFII |
|---|
| INTRAMUSCULAR PREFILLED |
| SYRINGE 720 MG/2.4ML, 960 |
| MG/3.2ML |
| ABILIFY MAINTENA 17, 18 |
| abiraterone acetate oral tablet 250 mg, 500 |
| mg 1 |
| acetylcysteine inhalation solution 10 %, 20 |
| % |
| acitretin |
| ACTIMMUNE |
| acyclovir sodium intravenous solution 50 |
| mg/ml |
| adalimumab-adbm (2 pen) 4 |
| adalimumab-adbm (2 syringe) subcutaneous |
| prefilled syringe kit 10 mg/0.2ml, 20 |
| mg/0.4ml, 40 mg/0.8ml 4 |
| adalimumab-adbm(cd/uc/hs strt) 4 |
| adalimumab-adbm(ps/uv starter) 4 |
| adapalene |
| adefovir dipivoxil |
| ADEMPAS |
| AKEEGA7 |
| albuterol sulfate inhalation nebulization |
| solution (2.5 mg/3ml) 0.083%, 0.63 |
| mg/3ml, 1.25 mg/3ml, 2.5 mg/0.5ml 278 |
| ALECENSA |
| alosetron hcl9 |
| alprazolam oral tablet 0.25 mg, 0.5 mg, 1 |
| mg, 2 mg 99 |
| ALUNBRIG11 |
| ambrisentan12 |
| AMJEVITA |
| AMJEVITA-PED 15KG TO <30KG 13 |
| amphotericin b intravenous solution |
| reconstituted 50 mg 278 |
| amphotericin b liposome intravenous |
| suspension reconstituted 50 mg 278 |
| ampicillin sodium injection solution |
| reconstituted 1 gm, 125 mg 278 |
| - |

| aprepitant oral capsule 125 mg, 40 mg, 80 & |
|---|
| 125 mg, 80 mg 278 |
| APTIOM |
| ARCALYST |
| ARIKAYCE16 |
| armodafinil |
| AUGTYRO 19 |
| AUSTEDO |
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| mg/2ml, 0.5 mg/2ml, 1 mg/2ml |
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| butalbital-apap-caffeine |
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| hydroxyzine pamoate | | |
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| 0.02 % | | |
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| ODOMZO | |
| OFEV | |
| OGSIVEO | |
| OJJAARA | |
| OMNITROPE | |
| ondansetron hcl oral solution 4 mg/5ml. | |
| ondansetron hel oral tablet 4 mg, 8 mg | |
| ondansetron oral tablet dispersible 4 mg, | |
| mg | |
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| OPSUMIT | 100 |
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| ORENCIA CLICKJECT | |
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| REPATHA PUSHTRONEX SYSTEM 1 | |
| REPATHA SURECLICK 1 | |
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| MG | |
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| REXULTI | |
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| ROZLYTREK ORAL CAPSULE 100 MC | |
| 200 MG | |
| RUBRACA | |
| rufinamide oral suspension | |
| rufinamide oral tablet | |
| RYBELSUS | |
| ΚΙ DAΓΙ | UU |

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| MG/2.4ML |
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| RECONSTITUTED 400 MG, 600 MG | |
| | |
| temazepam | |
| ТЕРМЕТКО | |
| teriparatide (recombinant) | |
| testosterone cypionate | |
| testosterone enanthate | |
| | |
| testosterone transdermal gel 10 mg/act ($12.5 \text{ mg/act}(19\%)$ 20.25 mg/1.25 mg | 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%) | |
| testosterone transdermal solution | |
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| trihexyphenidyl hcl | 98 |
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| TROPHAMINE INTRAVENOUS |
| SOLUTION 10 % |
| TRULICITY |
| TRUQAP |
| TUKYSA |
| TURALIO |
| TYMLOS |
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| XALKORI ORAL CAPSULE SPRINKLE |
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