# ACTIMMUNE

**Products Affected**

- Actimmune

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Chronic granulomatous disease - prescribed by or in consultation with an immunologist, hematologist or infectious disease specialist. Malignant osteopetrosis- prescribed by or in consultation with an endocrinologist or hematologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic granulomatous disease - approve if diagnosis has been established by a molecular genetic test identifying a gene-related pathogenic variant linked to chronic granulomatous disease. Malignant osteopetrosis, severe - approve if pt has had radiographic (X-ray) imaging demonstrating skeletal features related to osteopetrosis or pt had a molecular genetic test identifying a gene-related pathogenic variant linked to severe, malignant osteopetrosis. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ADALIMUMAB

**Products Affected**

- Cyltezo(CF)
- Cyltezo(CF) Pen
- Cyltezo(CF) Pen Crohn's-UC-HS
- Cyltezo(CF) Pen Psoriasis-UV

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another biologic DMARD or targeted synthetic DMARD. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Initial therapy only: CD-6 years and older, UC-5 years and older, AS/PsA/RA/PP/ Pyoderma gangrenosum/ sarcoidosis/ scleritis/ sterile corneal ulceration/ non-radiographic axial spondyloarthritis-18 years and older, JIA/UV/Behcet's disease-2 years and older, HS-12 years and older |
| **Prescriber Restrictions** | Initial therapy only for all dx, prescribed by or in consultation with one of the following specialists-RA/JIA/JRA/Ankylosing spondylitis/nr-axSpA, rheumatologist. PsA, rheumatologist or dermatologist. PP, dermatologist. UC/ CD, gastroenterologist. HS/pyoderma gangrenosum - dermatologist.UV/scleritis/sterile corneal ulceration-ophthalmologist. Behcet's-rheum, derm, ophthalmol, gastro, neuro. Sarcoidosis, pulm, ophthalmol, derm. |
| **Coverage Duration** | Approve through end of plan year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL THERAPY: CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA (one of A, B, C, D, or E): A) tried one other systemic therapy (e.g., MTX, sulfasalazine, leflunomide, NSAID), B) tried a biologic (e.g., etanercept, abatacept, infliximab, anakinra, tocilizumab), C) will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide, D) patient has absolute contraindication to MTX, sulfasalazine, or leflunomide, or E) patient has aggressive disease. HIDRADENITIS SUPPURATIVA (HS): tried one other therapy (e.g., intralesional or oral CS, systemic antibiotics, isotretinoin). PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., MTX, cyclosporine (CSA), acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of a biologic will also count) or B) contraindication to MTX. RHEUMATOID ARTHRITIS (RA): tried one conventional synthetic DMARD for at least 3 months (Note: a 3-month trial of a biologic will also count). ULCERATIVE COLITIS (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. BEHCET'S DISEASE (A or B): A) tried one conventional therapy (e.g., systemic CS, azathioprine, MTX, CSA, chlorambucil, cyclophosphamide, interferon alfa), or B) has ophthalmic manifestations. SARCOIDOSIS (A and B): A) tried one CS, and B) tried one immunosuppressant (e.g. MTX, mycophenolate mofetil, chlorambucil, thalidomide, infliximab, chloroquine). SCLERITIS/STERILE CORNEAL ULCERATION: tried one other therapy (e.g. CS, CSA). NON RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation defined as either (A or B): A) C-reactive protein elevated beyond upper limit of normal, or B) sacroiliitis on MRI. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Behcet's disease, pyoderma gangrenosum, sarcoidosis, scleritis/sterile corneal ulceration, non-radiographic axial spondyloarthritis. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ADEMPAS

**Products Affected**

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Phosphodiesterase Inhibitors Used for Pulmonary Hypertension or Other Soluble Guanylate Cyclase Stimulators. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For PAH - must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# AIMOVIG

**Products Affected**

- Aimovig Autoinjector

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with another cGRP inhibitor for migraine headache prevention |
| **Required Medical Information** | Diagnosis, number of migraine headaches per month |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Aimovig, the pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Aimovig was initiated. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# AKEEGA

**Products Affected**

- Akeega

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate cancer- Approve if the patient meets the following (A, B, C, and D): A)Patient has metastatic castration-resistant prostate cancer, AND B)Patient has a BReast CAncer (BRCA) mutation, AND C)The medication is used in combination with prednisone, AND D)Patient meets one of the following (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog, Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), and Orgovyx (relugolix tablets).OR ii. Patient has had a bilateral orchiectomy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ALECENSA

**Products Affected**

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Pediatric diffuse high grade glioma- less than or equal to 21 years old, All others- 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-small cell lung cancer-approve if the patient has both (A and B): A) either (i or ii): i) medication is used as adjuvant treatment following tumor resection (note: for tumors greater than or equal to 4 cm or node positive) or ii) advanced or metastatic disease and B) anaplastic lymphoma kinase (ALK)-positive disease as detected by an approved test. Anaplastic large cell lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease and (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory Myofibroblastic Tumor- pt has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) pt has advanced, recurrent or metastatic disease, or (ii) tumor is inoperable. Large B-Cell Lymphoma- pt has ALK-positive disease AND pt has relapsed or refractory disease. Pediatric diffuse high grade glioma- approve if (A and B): A) ALK-positive disease, and B) either (i or ii): i) medication is used as adjuvant treatment AND tumor is not diffuse midline glioma, H3 K27-altered or pontine location, or ii) medication is used for recurrent or progressive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Anaplastic large cell lymphoma, Erdheim Chester disease, Inflammatory Myofibroblastic Tumor, Large B-Cell Lymphoma, Pediatric Diffuse High Grade Glioma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ALOSETRON

**Products Affected**

- alosetron

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ALPHA 1 PROTEINASE INHIBITORS

**Products Affected**

- Prolastin-C intravenous solution

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Alpha1-Antitrypsin Deficiency with Emphysema (or Chronic Obstructive Pulmonary Disease)-approve if the patient has a baseline (pretreatment) AAT serum concentration of less than 80 mg/dL or 11 micromol/L. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ALUNBRIG

**Products Affected**

- Alunbrig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | ALK status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Erdheim-Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK positive disease and has advanced, recurrent or metastatic disease or the tumor is inoperable. NSCLC, must be ALK-positive, as detected by an approved test, have advanced or metastatic disease and patients new to therapy must have a trial of Alecensa or Lorbrena prior to approval of Alunbrig. Peripheral T-Cell Lymphoma- approve if patient has ALK-positive anaplastic large cell lymphoma (ALCL). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Erdheim-Chester disease, Inflammatory myofibroblastic tumor (IMT), Peripheral T-Cell Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# AMBRISENTAN

**Products Affected**

- ambrisentan

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath |
| **Age Restrictions** | |
| **Prescriber Restrictions** | For treatment of pulmonary arterial hypertension, ambrisentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ANTIFUNGALS (IV)

**Products Affected**

- voriconazole

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ANTI-OBESITY AGENTS

**Products Affected**

- ADIPEX-P 37.5 MG TABLET
- BENZPHETAMINE HCL 50 MG TABLET (Rx)
- DIETHYLPROPION 25 MG TABLET
- DIETHYLPROPION ER 75 MG TABLET
- LOMAIRA 8 MG TABLET
- ORLISTAT 120 MG CAPSULE
- PHENDIMETRAZINE 35 MG TABLET
- PHENDIMETRAZINE ER 105 MG CAP
- PHENTERMINE 15 MG CAPSULE
- PHENTERMINE 30 MG CAPSULE
- PHENTERMINE 37.5 MG CAPSULE
- PHENTERMINE 37.5 MG TABLET
- PHENTERMINE-TOPIRAMATE ER 11.25-69 MG CAPSULE
- PHENTERMINE-TOPIRAMATE ER 15-92 MG CAPSULE
- PHENTERMINE-TOPIRAMATE ER 3.75-23 MG CAPSULE
- PHENTERMINE-TOPIRAMATE ER 7.5-46 MG CAPSULE
- SAXENDA 18 MG/3 ML PEN
- WEGOVY 0.25 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 0.5 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 1 MG/0.5 ML PEN OUTER,SUV
- WEGOVY 1.7 MG/0.75 ML PEN OUTER,SUV
- WEGOVY 2.4 MG/0.75 ML PEN OUTER,SUV
- XENICAL 120 MG CAPSULE
- ZEPBOUND 10 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 10 MG/0.5 ML VIAL
- ZEPBOUND 12.5 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 15 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 2.5 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 2.5 MG/0.5 ML VIAL SUV, P/F, OUTER
- ZEPBOUND 5 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 5 MG/0.5 ML VIAL SUV, P/F, OUTER
- ZEPBOUND 7.5 MG/0.5 ML PEN SUV, P/F, OUTER
- ZEPBOUND 7.5 MG/0.5 ML VIAL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of more than one weight loss medication in this drug class concurrently. Concurrent use of an anti-obesity GLP-1 agonist (Wegovy, Saxenda or Zepbound) with a DPP4 inhibitor. |

| PA Criteria | Criteria Details |
|---|---|
| **Required Medical Information** | Initial: For patients age greater than or equal to12 years to less than 18 years, must have one of the following (a or b): a) an initial body mass index [BMI] per CDC growth charts at the 95th percentile or greater for age and sex (obesity), OR b) BMI in the 85th - 94th percentile (overweight) per CDC growth charts AND at least one of the following weight-related coexisting conditions: diabetes, sleep apnea, hypertension, OR dyslipidemia. For patients 18 years and older must have one of the following (a or b): a) an initial BMI greater than or equal to than 30 kg/m^2 , OR b) BMI greater than or equal to than 27 kg/m2 but less than 30 kg/m^2 AND at least one of the following: hypertension, coronary artery disease, diabetes, dyslipidemia, or sleep apnea, OR for Wegovy this medication is being prescribed for cardiovascular risk reduction in members with prior myocardial infarction, prior stroke, or peripheral arterial disease. Renewal: For patient's age greater than or equal to 12 years to less than 18 years, prescriber provides clinical documentation showing that the patient has maintained or improved BMI percentile per CDC growth charts from baseline weight at initiation of therapy. For adults age greater than or equal to18 years, prescriber provides clinical documentation showing that the patient has maintained a weight loss of greater than or equal to 5% from baseline weight at initiation of therapy. |
| **Age Restrictions** | Wegovy, Xenical, Saxenda, phentermine/topiramate: 12 years or older. Phentermine: 17 years or older. Benzphetamine, diethylpropion, phendimetrazine, Zepbound: 18 years or older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Initial: 6 months, Renewal: 6 months |
| **Other Criteria** | For patients with an eating disorder, prescriber attests that treatment has been optimized and confirms the safety and appropriateness of this anti-obesity treatment. Prescriber attests that metabolic or other reasons for obesity/symptoms have been ruled out or diagnosed and treated (e.g., thyroid dysfunction, diabetes, sleep apnea, etc.). Prescriber attests to patient's absence of any contraindications to use of the requested product, including pregnancy, lactation, a personal or family history of medullary thyroid cancer or multiple endocrine neoplasia type II. Prescriber attests medication therapy is part of a total treatment plan including diet and exercise/activity as appropriate for the patient's ability. Prescriber attests that the patient has been informed weight may return with cessation of medication unless healthy lifestyle diet and activity changes, as appropriate for the patient's ability, are permanently adopted. |
| **Indications** | Some FDA-approved Indications Only. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ARCALYST

**Products Affected**

- Arcalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent biologic therapy |
| **Required Medical Information** | |
| **Age Restrictions** | Initial tx CAPS/Pericarditis-Greater than or equal to 12 years of age. |
| **Prescriber Restrictions** | Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. DIRA initial-rheum, geneticist, derm, or a physician specializing in the treatment of autoinflammatory disorders. Pericarditis-cardiologist or rheum |
| **Coverage Duration** | CAPS-3 mos initial, 1 yr cont. DIRA-6 mos initial, 1 yr cont. Pericard-3 mos initial, 1 yr cont |
| **Other Criteria** | INITIAL THERAPY: DEFICIENCY OF INTERLEUKIN-1 RECEPTOR ANTAGONIST (DIRA) [ all of A, B, and C]: A) weighs at least 10 kg, B) genetic test has confirmed bi-allelic pathogenic variants in the IL1RN gene, and C) had clinical benefit with anakinra subcutaneous injection. PERICARDITIS: pericarditis is recurrent. CONTINUATION THERAPY: ALL INDICATIONS: patient had a positive response to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ARIKAYCE

**Products Affected**

- Arikayce

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous medication history (as described in Other Criteria field) |
| **Age Restrictions** | MAC-18 years and older (initial therapy) |
| **Prescriber Restrictions** | MAC initial-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | INITIAL THERAPY: MYCOBACTERIUM AVIUM COMPLEX (MAC) LUNG DISEASE (all of A, B, and C): A) positive sputum culture for MAC [Note: any positive sputum culture taken after completion of a background multidrug regimen (throughout, see Example 1 below) fulfills this criterion], B) MAC isolate is susceptible to amikacin, and C) Arikayce will be used in combination with a background multidrug regimen. CONTINUATION THERAPY: MAC LUNG DISEASE (A and B): A) Arikayce prescribed in combination with a background multidrug regimen and B) patient meets one of the following (a or b): a) patient has not achieved negative sputum cultures for MAC or b) patient has achieved negative sputum cultures for MAC for less than 12 months. Example 1: background multidrug regimen example - a macrolide (azithromycin or clarithromycin), ethambutol, and a rifamycin (rifampin or rifabutin). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# AUBAGIO

**Products Affected**

- teriflunomide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of teriflunomide with other disease-modifying agents used for multiple sclerosis (MS) |
| **Required Medical Information** | Relapsing form of MS, to include, clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# AUGTYRO

**Products Affected**

- Augtyro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC - 18 years and older, Solid tumors - 12 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Non-Small Cell Lung Cancer-approve if the patient has locally advanced or metastatic disease, patient has ROS1-positive non-small cell lung cancer and the mutation was detected by an approved test. Solid tumors - approve if tumor is positive for neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND tumor is locally advanced or metastatic or surgical resection will likely result in severe morbidity AND disease has progressed following treatment or there are no satisfactory alternative therapies. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# AVMAPKI-FAKZYNJA

**Products Affected**

- Avmapki-Fakzynja

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | OVARIAN, FALLOPIAN TUBE OR PRIMARY PERITONEAL CANCER- ALL of the following (A, B and C): A) Patient has recurrent low-grade serous cancer, AND B) The cancer has a KRAS mutation, AND C) Patient has tried at least one systemic therapy. Note: Examples of systemic therapy include one or more of the following medications: paclitaxel, carboplatin, bevacizumab, letrozole, anastrozole, or exemestane. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Fallopian Tube or Primary Peritoneal Cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# AYVAKIT

**Products Affected**

- Ayvakit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | GIST-approve if the tumor is positive for platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation or if the patient has tried two of the following: Gleevec (imatinib), Sutent (sunitinib), Sprycel (dasatinib), Stivarga (regorafenib) or Qinlock (ripretinib). Myeloid/Lymphoid Neoplasms with eosinophilia-approve if the tumor is positive for PDGFRA D842V mutation. Systemic mastocytosis-Approve if the patient has a platelet count greater than or equal to 50,000/mcL and patient has either indolent systemic mastocytosis or one of the following subtypes of advanced systemic mastocytosis-aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm or mast cell leukemia. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloid/Lymphoid neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BALVERSA

**Products Affected**

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Urothelial Carcinoma, locally advanced or metastatic-approve if the patient has susceptible fibroblast growth factor receptor 3 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy, other chemotherapy or checkpoint inhibitor therapy. Pancreatic adenocarcinoma- approve if (A, B, C and D): A) patient has a fibroblast growth factor receptor (FGFR) genetic alterations, and B) locally advanced, recurrent or metastatic disease, and C) medication is used for subsequent therapy and D) medication is used as a single agent. NSCLC- approve if patient has metastatic disease and FGFR alterations. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Pancreatic adenocarcinoma, non-small cell lung cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BENLYSTA

**Products Affected**

- Benlysta subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BESREMI

**Products Affected**

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BETASERON/EXTAVIA

**Products Affected**

- Betaseron subcutaneous kit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or after consultation with a neurologist or an MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BEXAROTENE (ORAL)

**Products Affected**

- bexarotene

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BEXAROTENE (TOPICAL)

**Products Affected**

- bexarotene

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cutaneous T-Cell lymphoma-approve if pt has cutaneous manifestations/lesions. Adult T-Cell Leukemia/Lymphoma- approve if the patient has smoldering symptomatic subtype and this medication is used as first-line therapy. Primary cutaneous B-Cell lymphoma-approve if used as skin-directed therapy for either (a or b): a) primary cutaneous marginal zone lymphoma or b) follicle center lymphoma. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Adult T-Cell Leukemia/Lymphoma, Primary Cutaneous B-Cell Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# BOSENTAN

**Products Affected**

- bosentan oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) WHO Group 1, results of right heart cath |
| **Age Restrictions** | |
| **Prescriber Restrictions** | For treatment of pulmonary arterial hypertension, bosentan must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH - prescribed by or in consultation with a cardiologist or pulmonologist |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving bosentan for CTEPH. Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Chronic thromboembolic pulmonary hypertension (CTEPH) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BOSULIF

**Products Affected**

- Bosulif

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | ALL - 15 years and older. Myeloid/lymphoid neoplasms w eosinophilia- 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | CML-approve if the patient has Ph-positive or BCR::ABL1-positive CML. For Ph-positive ALL-approve if pt has tried at least one other tyrosine kinase inhibitor for Ph+ ALL. Myeloid/lymphoid neoplasms with eosinophilia - approve if tumor has an ABL1 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia, myeloid/lymphoid neoplasms with eosinophilia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# BRAFTOVI

**Products Affected**

- Braftovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, BRAF V600 status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation. Colon or Rectal cancer-approve if the patient meets the following (A and B): A) The patient has BRAF V600E mutation-positive disease AND B) meets (i or ii): i) will be used as first-line systemic therapy for metastatic disease in combination with Erbitux (cetuximab intravenous infusion) and mFOLFOX6 (5-FU, leucovorin, and oxaliplatin) or ii) patient has previously received a chemotherapy regimen for colon or rectal cancer and this is prescribed in combination with Erbitux or Vectibix (panitumumab intravenous infusion). NSCLC- approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Mektovi (binimetinib tablets). Appendiceal adenocarcinoma-approve if (A, B and C): A) BRAF V600E mutation-positive, and B) used as subsequent therapy for advanced or metastatic disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Appendiceal adenocarcinoma |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# BRUKINSA

**Products Affected**

- Brukinsa oral capsule

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Follicular Lymphoma - approve if pt tried at least two other systemic regimens and will use this in combination with Gazyva (obinutuzumab intravenous infusion). Mantle Cell Lymphoma - approve if patient meets (A or B): A. meets both of the following: i. has tried Calquence or Imbruvica, AND ii. one of the following (1, 2, 3): 1) tried at least one other line of systemic regimen, or 2) is not a candidate for a systemic regimen, or 3) will use this medication in combination with rituximab, B. patient has TP53 mutation and this medication is used as induction therapy in combination with Venclexta (venetoclax tablets) and Gazyva (obinutuzumab intravenous infusion). CLL/SLL- approve if the patient has tried Calquence or Imbruvica. Marginal zone lymphoma - approve if the patient has tried at least one prior anti-CD20 monoclonal anti-body-based systemic regimen and patient has tried Calquence or Imbruvica. Waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma - approve if patient has tried Imbruvica. Hairy Cell Leukemia - approve if the patient has progressive disease after relapsed or refractory therapy and has tried Imbruvica. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Hairy Cell Leukemia |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# C1 ESTERASE INHIBITORS

**Products Affected**

- Haegarda

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II], Prophylaxis, Initial Therapy: approve if the patient has HAE type I or type II confirmed by low levels of functional C1-INH protein (less than 50 percent of normal) at baseline and lower than normal serum C4 levels at baseline. Patient is currently taking Haegarda for prophylaxis - approve if the patient meets the following criteria (i and ii): i) patient has a diagnosis of HAE type I or II, and ii) according to the prescriber, the patient has had a favorable clinical response since initiating Haegarda as prophylactic therapy compared with baseline. For patients with HAE with normal C1 inhibitor, EITHER 1) Patient tested positive for an F12, angiopoietin-1, plasminogen, kininogen-1 (KNG1), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine therapy for at least one month. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# CABOMETYX

**Products Affected**

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, histology, RET gene rearrangement status for NSCLC |
| **Age Restrictions** | Neuroendocrine tumor/Thyroid carcinoma-12 years and older, other dx (except bone cancer)-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Renal Cell Carcinoma-Approve if the patient has relapsed or stage IV disease. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima). Bone cancer-approve if the patient has Ewing sarcoma or osteosarcoma and has tried at least one previous systemic regimen. Thyroid carcinoma-approve if the patient has differentiated thyroid carcinoma, patient is refractory to radioactive iodine therapy and the patient has tried Lenvima or sorafenib. Endometrial carcinoma-approve if the patient has tried one systemic regimen. GIST-approve if the patient has tried two of the following-imatinib, Ayvakit, sunitinib, dasatinib, Stivarga or Qinlock. NSCLC-approve if the patient has RET rearrangement positive tumor and has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Neuroendocrine tumors- approve if (A, B, C and D): A) pt has locally advanced, unresectable, or metastatic disease, and B) patient has well-differentiated neuroendocrine tumors, and C) patient has pancreatic or extra-pancreatic neuroendocrine tumors and D) the medication will be used as subsequent therapy. Adrenal gland tumor- approve if pt has locoregional unresectable or metastatic adrenocortical carcinoma. Pheochromocytoma/paraganglioma-approve if pt has locally unresectable disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Patients with Non-Small Cell Lung Cancer, Gastrointestinal stromal tumors (GIST), Bone cancer, Endometrial carcinoma, Adrenal gland tumor, Pheochromocytoma/paraganglioma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# CALQUENCE

**Products Affected**

- Calquence (acalabrutinib mal)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CLL and SLL-approve. Mantle Cell Lymphoma- approve if the patient meets (A or B): A) has tried at least one systemic regimen or is not a candidate for a systemic regimen (e.g., rituximab, dexamethasone, cytarabine, carboplatin, cisplatin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, prednisone, methotrexate, bendamustine, bortezomib, or lenalidomide) or B) this medication is used in combination with rituximab. Marginal Zone Lymphoma-approve if patient has tried at least one systemic regimen (e.g., bendamustine, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone, lenalidomide, or chlorambucil). Waldenstrom Macroglobulinamia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen (e.g., Brukinsa [zanubrutinib capsules], Imbruvica [ibrutinib tablets and capsules], rituximab, bendamustine, cyclophosphamide, dexamethasone, bortezomib, fludarabine, or cladribine) |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma, Marginal zone lymphoma. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# CAPRELSA

**Products Affected**

- Caprelsa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | MTC - approve.  DTC - approve if refractory to radioactive iodine therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CARGLUMIC ACID

**Products Affected**

- carglumic acid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases |
| **Coverage Duration** | NAGS-Pt meets criteria no genetic test - 3mo. Pt had genetic test - 12mo, other-approve 7 days |
| **Other Criteria** | N-Acetylglutamate synthase deficiency with hyperammonemia-Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency or if the patient has hyperammonemia. Propionic Acidemia or Methylmalonic Acidemia with Hyperammonemia, Acute Treatment-approve if the patient's plasma ammonia level is greater then or equal to 50 micromol/L and the requested medication will be used in conjunction with other ammonia-lowering therapies. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) (generic carglumic acid) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CAYSTON

**Products Affected**

- Cayston

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist, infectious diseases specialist or a physician who specializes in the treatment of cystic fibrosis. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has Pseudomonas aeruginosa in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CLOBAZAM

**Products Affected**

- clobazam oral suspension
- clobazam oral tablet
- Sympazan

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other medications tried |
| **Age Restrictions** | 2 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Lennox-Gastaut Syndrome, initial therapy-patient has tried and/or is concomitantly receiving one of the following: lamotrigine, topiramate, rufinamide, felbamate, Fintepla, Epidiolex or valproic acid. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Dravet Syndrome and treatment-refractory seizures/epilepsy |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# CLOMIPRAMINE

**Products Affected**

- clomipramine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Request meets either (1 and 2) OR (3 and 4): 1) The requested drug is being prescribed for one of the following: a) Obsessive-Compulsive Disorder (OCD), b) Panic Disorder, c) Autistic disorder, AND 2) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to any of the following: a) a serotonin and norepinephrine reuptake inhibitor (SNRI), b) a selective serotonin reuptake inhibitor (SSRI), OR 3) The requested drug is being prescribed for Depression AND 4) The patient has experienced an inadequate treatment response, intolerance, or the patient has a contraindication to two of the following: a) serotonin and norepinephrine reuptake inhibitors (SNRIs), b) selective serotonin reuptake inhibitors (SSRIs), c) mirtazapine, d) bupropion |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Depression, Panic Disorder, Autistic disorder |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# COMETRIQ

**Products Affected**

- Cometriq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | MTC - approve. Non-Small Cell Lung Cancer-approve if patient meets (A, B and C): A) recurrent, advanced, or metastatic disease, B) has RET gene rearrangement-positive tumor, and C) has progressed on one of the first-line therapies, Gavreto (pralsetinib capsules) or Retevmo (selpercatinib capsules or tablets). Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy and patient has tried tried Lenvima (lenvatinib capsules) or sorafenib tablets. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# COPIKTRA

**Products Affected**

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic Lymphocytic Leukemia/ Small Lymphocytic Lymphoma - approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)- based regimen. T-cell lymphoma- For peripheral T-cell lymphoma, approve. For breast implant-associated anaplastic large cell lymphoma, or hepatosplenic T-cell lymphoma, approve if the patient has relapsed or refractory disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | T-cell Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# COSENTYX

**Products Affected**

- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)
- Cosentyx subcutaneous syringe 75 mg/0.5 mL
- Cosentyx UnoReady Pen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis and previous medications use |
| **Age Restrictions** | PP-6 yr and older.AS/Spondy/HS initial - 18 years of age and older. PsA-2 years and older. Enthesitis-4 years and older |
| **Prescriber Restrictions** | PP initial-presc/consult derm. PsA initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS/spondylo/enthesitis initial- by or in consultation with rheumatologist. HS initial - by or in consult w/ dermatologist |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: HIDRADENITIS SUPPURATIVA (HS): tried at least one other therapy (e.g. systemic antibiotics, isotretinoin). NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: objective signs of inflammation and meets a or b: a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI. PLAQUE PSORIASIS (PP) [A or B]: A) tried at least one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (Note: a trial of at least one biologic that is not Cosentyx or a Cosentyx biosimilar also counts) or B) contraindication to MTX. CONTINUATION THERAPY: ALL INDICATIONS: patient has experienced benefit from the medication. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# COTELLIC

**Products Affected**

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf AND patient has BRAF V600 mutation positive disease. CNS Cancer-approve if the patient has BRAF V600 mutation-positive disease AND medication is being used for one of the following situations (i, ii, or iii): i. Adjuvant treatment of one of the following conditions (a, b, or c): a) Pilocytic astrocytoma OR b) Pleomorphic xanthoastrocytoma OR c) circumscribed ganglioglioma/neuroglioma/glioneuronal tumor OR ii. Recurrent or progressive disease for one of the following conditions (a, b or c): a) high grade glioma, b) circumscribed glioma OR c) Glioblastoma, OR iii. Melanoma with brain metastases AND medication with be taken in combination with Zelboraf (vemurafenib tablets). Histiocytic Neoplasm-approve if the patient meets one of the following (i, ii, or iii): i. Patient has Langerhans cell histiocytosis and one of the following (a, b, or c): a) Multisystem disease OR b) Pulmonary disease OR c) Central nervous system lesions OR ii. Patient has Erdheim Chester disease OR iii. Patient has Rosai-Dorfman disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Central Nervous System Cancer |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | No |

# CRESEMBA (ORAL)

**Products Affected**

- Cresemba oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 3 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Candidiasis of the esophagus - HIV infection, sepsis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CYSTEAMINE (OPHTHALMIC)

**Products Affected**

- Cystaran

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# CYSTEAMINE (ORAL)

**Products Affected**

- Cystagon

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use of Cystagon and Procysbi |
| **Required Medical Information** | Diagnosis, genetic tests and lab results (as specified in the Other Criteria field) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist or a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cystinosis, nephropathic-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic or likely pathogenic variants in the CTNS gene OR white blood cell cystine concentration above the upper limit of the normal reference range for the reporting laboratory. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DALFAMPRIDINE

**Products Affected**

- dalfampridine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DAURISMO

**Products Affected**

- Daurismo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, medications that will be used in combination, comorbidities |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML - approve if Daurismo will be used in combination with cytarabine. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DEFERASIROX

**Products Affected**

- deferasirox oral tablet
- deferasirox oral tablet, dispersible

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Serum ferritin level |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve is the patient is benefiting from therapy as confirmed by the prescribing physician. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DIACOMIT

**Products Affected**

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Documentation of diagnosis. |
| **Age Restrictions** | 6 months and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome-Initial therapy-approve if the patient is concomitantly receiving clobazam or is unable to take clobazam due to adverse events. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DIMETHYL FUMARATE

**Products Affected**

- dimethyl fumarate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS). |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist or MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DOPTELET

**Products Affected**

- Doptelet (10 tab pack)
- Doptelet (15 tab pack)
- Doptelet (30 tab pack)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# DRONABINOL

**Products Affected**

- dronabinol

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# DUPIXENT

**Products Affected**

- Dupixent Pen
- Dupixent Syringe subcutaneous syringe 200 mg/1.14 mL, 300 mg/2 mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# EMGALITY

**Products Affected**

- Emgality Pen
- Emgality Syringe subcutaneous syringe 120 mg/mL

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with another cGRP inhibitor for migraine headache prevention |
| **Required Medical Information** | Diagnosis, number of migraine or cluster headaches per month |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Cluster headache tx-6 months, migraine prevention-1 year |
| **Other Criteria** | Migraine headache prevention-Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) If pt is currently taking Emgality, pt has had significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Emgality was initiated. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ENBREL

**Products Affected**

- Enbrel Mini
- Enbrel subcutaneous solution
- Enbrel subcutaneous syringe
- Enbrel SureClick

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with biologic therapy or targeted synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous therapies tried. |
| **Age Restrictions** | Initial therapy: AS/RA- 18 years and older, JIA/PsA/Behcet's-2 years and older, GVHD-6 years and older, PP-4 years and older |
| **Prescriber Restrictions** | Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center.Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist. |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/JUVENILE IDIOPATHIC ARTHRITIS (JIA)/JRA/ANKYLOSING SPONDYLITIS: approve if the patient has tried one preferred adalimumab product (a trial of a non-preferred adalimumab also counts). PLAQUE PSORIASIS (PP)/PSORIATIC ARTHRITIS: approve if the patient has tried one preferred adalimumab product (a non-preferred adalimumab also counts), unless the patient is less than 18 years of age. GRAFT VERSUS HOST DISEASE (GVHD): approve. BEHCET'S: tried at least one conventional therapy (e.g., systemic corticosteroid, immunosuppressant, interferon alfa, mycophenolate), adalimumab, or infliximab. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Graft versus host disease (GVHD), Behcet's disease |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# ENDARI

**Products Affected**

- glutamine (sickle cell)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prescriber specialty |
| **Age Restrictions** | Greater than or equal to 5 years of age |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a physician who specializes in sickle cell disease (e.g., a hematologist) |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# EPIDIOLEX

**Products Affected**

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapies |
| **Age Restrictions** | Patients 1 year and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs or if the patient has tried or is concomitantly receiving one of Diacomit or clobazam or Fintepla. Lennox Gastaut Syndrome (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Tuberous Sclerosis Complex (initial therapy)-approve if the patient has tried or is concomitantly receiving at least two other antiseizure drugs. Refractory epilepsy (initial therapy)-approve if patient tried or is concomitantly receiving at least two other antiseizure drugs. Continuation of therapy for all indications-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Refractory epilepsy |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# EPOETIN ALFA

**Products Affected**

- Retacrit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | MDS anemia = 18 years of age and older |
| **Prescriber Restrictions** | MDS anemia, myelofibrosis- prescribed by or in consultation with, a hematologist or oncologist. |
| **Coverage Duration** | Chemo-6m,Transfus-1m, CKD-1yr, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr |
| **Other Criteria** | Anemia in a pt with Chronic Kidney Disease (CKD) not on dialysis- for initial therapy, approve if hemoglobin (Hb) is less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children, or for continuation of therapy in a pt currently on an erythropoiesis-stimulating agent (ESA) approve if Hb is less than or equal to 12 g/dL. Anemia in a pt with cancer due to chemotherapy- approve if pt is currently receiving myelosuppressive chemo as a non-curative treatment and (for initial therapy) Hb is less than 10.0 g/dL or (if currently on ESA) Hb is less than or equal to 12.0 g/dL. Anemia in HIV with zidovudine- for initial therapy, approve if Hb is less than 10.0 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA, approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - Approve if Hb is less than or equal to 13, AND surgery is elective, nonvascular and non-cardiac AND pt is unwilling or unable to donate autologous blood prior to surgery. MDS- for initial therapy, approve if Hb is less than 10 g/dL or serum erythropoietin level is 500 mU/mL or less, or for continuation of therapy in a pt currently on ESA approve if Hb is 12.0 g/dL or less. Myelofibrosis- for Initial therapy approve if patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 mU/mL, or for continuation of therapy in pt currently on ESA hemoglobin is less than or equal to 12g/dL. Anemia in patients with chronic renal failure on dialysis - deny under Medicare Part D (claim should be submitted under the ESRD bundled payment benefit). |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Anemia due to myelodysplastic syndrome (MDS), Myelofibrosis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ERIVEDGE

**Products Affected**

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ERLEADA

**Products Affected**

- Erleada

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ERLOTINIB

**Products Affected**

- erlotinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Advanced or Metastatic NSCLC, approve if the patient has EGFR mutation positive non-small cell lung cancer as detected by an approved test. Note-Examples of EGFR mutation-positive non-small cell lung cancer include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. RCC, approve if the patient meets (A, B, and C): A) has stage IV or relapsed non-clear cell histology RCC and B) has advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated renal cell carcinoma and C) erlotinib will be used in combination with bevacizumab. Bone cancer-approve if the patient has chordoma and has tried at least one previous therapy. Pancreatic cancer-approve if the medication is used in combination with gemcitabine and if the patient has locally advanced, metastatic or recurrent disease. Vulvar cancer-approve if the patient has advanced, recurrent or metastatic disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Renal Cell Carcinoma, vulvar cancer and Bone Cancer-Chordoma. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# EVEROLIMUS

**Products Affected**

- everolimus (antineoplastic)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# FINGOLIMOD

**Products Affected**

- fingolimod

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of fingolimod with other disease-modifying agents used for multiple sclerosis (MS). |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | 10 years and older |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a neurologist or an MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# FINTEPLA

**Products Affected**

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an neurologist (initial therapy) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Dravet Syndrome-Initial therapy-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs or patient has tried or is concomitantly receiving Epidiolex, Clobazam or Diacomit. Dravet Syndrome-Continuation-approve if the patient is responding to therapy. Lennox-Gastaut Syndrome, initial-approve if the patient has tried or is concomitantly receiving at least two other antiepileptic drugs. Lennox-Gastaut Syndrome, continuation-approve if the patient is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# FIRMAGON

**Products Affected**

- Firmagon kit w diluent syringe

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a oncologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Patients new to therapy, are required to try Eligard prior to approval of Firmagon. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# FLUCYTOSINE

**Products Affected**

- flucytosine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# FOTIVDA

**Products Affected**

- Fotivda

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Renal Cell Carcinoma (RCC)-approve if the patient has relapsed or Stage IV disease and has tried at least two other systemic regimens. Note: Examples of systemic regimens for renal cell carcinoma include axitinib tablets, axitinib + pembrolizumab injection, cabozantinib tablets, cabozantinib + nivolumab injection, sunitinib malate capsules, pazopanib tablets, sorafenib tablets, and lenvatinib capsules + everolimus. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# FRUZAQLA

**Products Affected**

- Fruzaqla

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Colon cancer, rectal cancer, or appendiceal cancer-Approve if the patient meets the following (A, B and C): A.Patient has advanced or metastatic disease, AND B. Patient meets (i or ii): i. has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease, or ii. patient is ineligible for or progressed on checkpoint inhibitor therapy (examples: Keytruda [pembrolizumab intravenous infusion] and Opdivo [nivolumab intravenous infusion]) and meets ONE of the following (a or b): a. has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or b. is polymerase epsilon/delta (POLE/POLD1) mutation positive, AND C. Patient has previously been treated with the following (i, ii, and iii): i.Fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, Note: Examples of fluoropyrimidine agents include 5-fluorouracil (5-FU) and capecitabine. AND ii.An anti-vascular endothelial growth factor (VEGF) agent, Note: Examples of anti-VEGF agents include bevacizumab. AND iii. If the tumor is RAS wild-type (KRAS wild-type and NRAS wild-type) [that is, the tumor or metastases are KRAS and NRAS mutation negative], the patient meets ONE of the following (a or b): a.According to the prescriber, anti-epidermal growth factor receptor (EGFR) therapy is NOT medically appropriate, OR b. The patient has received an anti-EGFR therapy. Note: Examples of anti-EGFR therapy includes Erbitux (cetuximab intravenous infusion) and Vectibix (panitumumab intravenous infusion). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Appendiceal cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# GAVRETO

**Products Affected**

- Gavreto

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC-18 years and older, thyroid cancer-12 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced, recurrent, or metastatic disease and rearranged during transfection (RET) fusion-positive disease detected by an Food and Drug Administration (FDA) approved test. Differentiated Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has RET fusion-positive or RET-mutation-positive disease AND disease requires treatment with systemic therapy AND the disease is radioactive iodine-refractory. Anaplastic thyroid cancer or Medullary Thyroid Cancer- pt has unresectable, recurrent, or metastatic disease AND pt has disease positive for RET pathogenic variant. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Medullary Thyroid Cancer, Anaplastic Thyroid Cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GEFITINIB

**Products Affected**

- gefitinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease and the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | NSCLC with EGFR L861Q, G719X, or S768I mutations. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GILOTRIF

**Products Affected**

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | NSCLC EGFR pos - For the treatment of advanced or metastatic non small cell lung cancer (NSCLC)-approve if the patient has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: examples of sensitizing EGFR mutation-positive NSCLC include the following mutations : exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S768I. NSCLC metastatic squamous cell must have disease progression after treatment with platinum based chemotherapy. Head and neck cancer-approve if the patient has non-nasopharyngeal head and neck cancer and the patient has disease progression on or after platinum based chemotherapy. (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan) |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Head and neck cancer |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# GLATIRAMER

**Products Affected**

- glatiramer
- Glatopa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other disease-modifying agent used for multiple sclerosis |
| **Required Medical Information** | Relapsing form of Multiple Sclerosis (MS), to include clinically-isolated syndrome, relapsing-remitting disease, and active secondary progressive disease |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or after consultation with a neurologist or an MS specialist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GLUCAGON-LIKE PEPTIDE-1 AGONISTS

**Products Affected**

- liraglutide
- Mounjaro
- Ozempic subcutaneous pen injector 0.25 mg or 0.5 mg (2 mg/3 mL), 1 mg/dose (4 mg/3 mL), 2 mg/dose (8 mg/3 mL)
- Rybelsus
- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GOMEKLI

**Products Affected**

- Gomekli

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NEUROFIBROMATOSIS TYPE 1- patient has or had symptomatic plexiform neurofibromas prior to starting Gomekli and the tumor is not amenable to complete resection. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GONADOTROPIN-RELEASING HORMONE AGONISTS - ONCOLOGY

**Products Affected**

- Eligard
- Eligard (3 month)
- Eligard (4 month)
- Eligard (6 month)
- leuprolide subcutaneous kit

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prostate cancer- prescribed by or in consultation with an oncologist or urologist. Head and neck-salivary gland tumors- prescribed by or in consultation with an oncologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Head and neck cancer-salivary gland tumor- approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Head and neck cancer- salivary gland tumors (Eligard only) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GRALISE

**Products Affected**

- gabapentin oral tablet extended release 24 hr

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# GROWTH HORMONES

**Products Affected**

- Omnitrope

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# HIGH RISK MEDICATIONS - ANTIPARKINSON AGENTS

**Products Affected**

- benztropine oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. For EPS (extrapyramidal symptoms): The patient has tried and experienced an inadequate treatment response, intolerance, or has a contraindication to the non-HRM alternative drug amantadine. For Parkinson's: The patient has tried and experienced an inadequate treatment response or intolerance to two of the following non-HRM alternative drugs: amantadine, carbidopa/levodopa, pramipexole, or ropinirole. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# HIGH RISK MEDICATIONS - BENZODIAZEPINES

**Products Affected**

- clorazepate dipotassium
- Diazepam Intensol
- diazepam oral solution 5 mg/5 mL (1 mg/mL)
- diazepam oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Procedure-related sedation = 1mo. All other conditions = 12 months. |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. For the management of anxiety disorders: 1) The requested drug is being used concurrently with a selective serotonin reuptake inhibitor (SSRI) or serotonin-norepinephrine reuptake inhibitor (SNRI) until the SSRI/SNRI becomes effective for the symptoms of anxiety, OR 2) The patient has experienced an inadequate treatment response, intolerance, or has a contraindication to at least two agents from the following drug classes: a) selective serotonin reuptake inhibitor (SSRI), b) serotonin-norepinephrine reuptake inhibitor (SNRI). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# HIGH RISK MEDICATIONS - CYPROHEPTADINE

**Products Affected**

- cyproheptadine oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. For rhinitis: the patient has tried and experienced an inadequate treatment response or intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Pruritus, spasticity due to spinal cord injury |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

**Products Affected**

- hydroxyzine HCl oral tablet
- hydroxyzine pamoate oral capsule 25 mg, 50 mg
- promethazine oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. For promethazine, for the treatment of emesis, approve if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant). For hydroxyzine, for rhinitis: the patient has tried and experienced an inadequate treatment response or intolerance to two of the following non-HRM alternative drugs: levocetirizine, azelastine nasal, fluticasone nasal, or flunisolide nasal. For hydroxyzine, for anxiety: the patient has tried and experienced an inadequate treatment response or intolerance to two of the following alternative drugs: buspirone, a selective serotonin reuptake inhibitor (SSRI), or a serotonin-norepinephrine reuptake inhibitor (SNRI). |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# HIGH RISK MEDICATIONS - PHENOBARBITAL

**Products Affected**

- phenobarbital

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for use in sedation/insomnia. |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For the treatment of seizures, approve only if the patient is currently taking phenobarbital. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested high-risk medication (HRM) for the patient and must confirm that they would still like to initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# HIGH RISK MEDICATIONS - SCOPOLAMINE

**Products Affected**

- scopolamine base

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Excessive salivation |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

**Products Affected**

- cyclobenzaprine oral tablet 10 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# HIGH RISK MEDICATIONS - TEMAZEPAM

**Products Affected**

- temazepam oral capsule 15 mg, 30 mg, 7.5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For all covered indications, approve if the prescriber confirms they have assessed risk versus benefit in prescribing this high-risk medication (HRM) for the patient and they would still like to initiate/continue therapy. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# IBRANCE

**Products Affected**

- Ibrance

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ICATIBANT

**Products Affected**

- icatibant

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50 percent of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant - the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ICLUSIG

**Products Affected**

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status |
| **Age Restrictions** | All indications except ALL - 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Acute lymphoblastic leukemia, Philadelphia chromosome positive or ABL-class translocation: approve if the patient meets (1, 2 or 3): 1) will use in combination with chemotherapy, or 2) ALL is T315I-positive, or 3) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib or dasatinib). Chronic myeloid leukemia, Philadelphia chromosome positive or BCR::ABL1-positive-approve if patient meets (1, 2 or 3): 1) CML is T315I-positive, or 2) pt tried at least one other tyrosine kinase inhibitor (examples: imatinib, dasatinib, nilotinib), or 3) pt has accelerated-phase or blast-phase CML and no other tyrosine kinase inhibitor is indicated. GIST - approve if the patient tried all of the following therapies first to align with NCCN recommendations which include: Imatinib or Ayvakit (avapritinib tablets), AND Sunitinib or Sprycel (dasatinib tablets), AND Stivarga (regorafenib tablets), AND Qinlock (ripretinib tablets). Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has ABL1 rearrangement or FGFR1 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Gastrointestinal Stromal Tumor, Myeloid/Lymphoid Neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# IDHIFA

**Products Affected**

- Idhifa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | IDH2-mutation status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | AML - approve if the patient is IDH2-mutation status positive as detected by an approved test |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# IMATINIB

**Products Affected**

- imatinib
- Imkeldi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. |
| **Age Restrictions** | ASM, DFSP, HES, MDS/MPD/Myeloid/Lymphoid Neoplasms/Kaposi Sarcoma/Cutaneous Melanoma-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For ALL-approve for Ph-positive or ABL-class translocation ALL. CML-approve for Ph-positive or BCR::ABL1-mutation positive CML. Kaposi's Sarcoma-approve if the patient has tried at least one regimen AND has relapsed or refractory disease. Pigmented villonodular synovitis/tenosynovial giant cell tumor (PVNS/TGCT)-patient has tried Turalio or Romvimza or according to the prescriber, the patient cannot take Turalio or Romvimza. Myelodysplastic/myeloproliferative disease-approve if the condition is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangements.Graft versus host disease, chronic-approve if the patient has tried at least one conventional systemic treatment (e.g., imbruvica). Cutaneous melanoma-approve if the patient has an activating KIT mutation, metastatic or unresectable melanoma, and has tried at least one systemic regimen. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement or an FIP1L1-PDGFRA or PDGFRB rearrangement. Approve Imkeldi if the patient has had a trial of imatinib tablets (brand or generic) dispersed in a glass of water or apple juice (per product labeling). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Chordoma, desmoid tumors (aggressive fibromatosis), metastatic or unresectable cutaneous melanoma with activating kit mutation, Kaposi's Sarcoma and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor, myeloid/lymphoid neoplasms with eosinophilia, GVHD, chronic. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# IMBRUVICA

**Products Affected**

- Imbruvica oral capsule
- Imbruvica oral suspension
- Imbruvica oral tablet 140 mg, 280 mg, 420 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | GVHD-1 year and older, other-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CLL- Approve. GVHD-Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], imatinib, low-dose methotrexate, sirolimus, mycophenolate mofetil, Jakafi [ruxolitinib tablets]). B-cell lymphoma-approve if the patient has tried at least one systemic regimen (e.g., cisplatin, cytarabine, rituximab, oxaliplatin, gemcitabine, ifosfamide, carboplatin, etoposide, or rituximab). Central nervous system Lymphoma (primary)- approve if the patient is not a candidate for or is intolerant to high-dose methotrexate OR has tried at least one therapy (e.g., methotrexate, rituximab, vincristine, procarbazine, cytarabine, thiotepa, carmustine, intrathecal methotrexate, cytarabine, or rituximab). Hairy Cell Leukemia - approve if the patient has tried at least two systemic regimens (cladribine, Nipent [pentostatin injection], rituximab, or Pegasys [peginterferon alfa-2a subcutaneous injection]). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Central Nervous System Lymphoma (Primary), Hairy Cell Leukemia, B-Cell Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# IMPAVIDO

**Products Affected**

- Impavido

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an infectious diseases specialist |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Ameba related infections: approve if the patient is being treated for an infection due to one of the following: Acanthameoba, Balamuthia mandrillaris, or Naegleria fowleri. Note: Examples of ameba related infections are Acanthamoeba keratitis, granulomatous amebic encephalitis (GAE), and primary amebic meningoencephalitis (PAM). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Ameba related infections |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INBRIJA

**Products Affected**

- Inbrija inhalation capsule, w/inhalation device

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Asthma, COPD, other chronic underlying lung disease |
| **Required Medical Information** | Diagnosis, medications that will be used in combination |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Approve if the patient is currently taking carbidopa-levodopa and is experiencing off episodes. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# INCRELEX

**Products Affected**

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Pediatric patients with closed epiphyses |
| **Required Medical Information** | For growth failure due to severe primary insulin-like growth factor-1 (IGF-1) deficiency or growth hormone (GH) gene deletion in patients who have developed neutralizing antibodies to GH, patient meets all of the following prior to beginning therapy with the requested drug (new starts only): 1) height 3 or more standard deviations (SD) below the mean for children of the same age and gender AND 2) basal IGF-1 level 3 or more SD below the mean for children of the same age and gender AND 3) provocative growth hormone test showing a normal or elevated growth hormone level. For growth failure due to severe primary IGF-1 deficiency or GH gene deletion in patients who have developed neutralizing antibodies to GH, continuation of therapy: patient is experiencing improvement. |
| **Age Restrictions** | 2 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INGREZZA

**Products Affected**

- Ingrezza
- Ingrezza Initiation Pk(tardiv)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | TD - Prescribed by or in consultation with a neurologist or psychiatrist. Chorea HD - prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chorea associated with Huntington's Disease- approve if diagnosis is confirmed by genetic testing (for example, an expanded HTT CAG repeat sequence of at least 36). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INLYTA

**Products Affected**

- Inlyta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Advanced Renal cell carcinoma-approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy. Soft tissue sarcoma-approve if the patient has alveolar soft part sarcoma and the medication will be used in combination with Keytruda (pembrolizumab). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Differentiated (i.e., papillary, follicular, and oncocytic) Thyroid Carcinoma, Soft tissue sarcoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INQOVI

**Products Affected**

- Inqovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myelodysplastic Syndrome With Myeloproliferative Neoplasm Overlap Syndrome |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# INREBIC

**Products Affected**

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis (MF), including Primary MF, Post-Polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient has higher-risk disease. Myeloid/Lymphoid Neoplasms with Eosinophilia-approve if the tumor has a JAK2 rearrangement. Accelerated or blast phase myeloproliferative neoplasm-approve if the patient has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloid/Lymphoid Neoplasms with Eosinophilia, accelerated or blast phase myeloproliferative neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ITOVEBI

**Products Affected**

- Itovebi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | BREAST CANCER (all of A, B, C, D, E and F): A. Patient meets ONE of the following (i or ii): i. Patient is a postmenopausal female, OR ii. Patient meets BOTH of the following (a and b): a. Patient is a pre/perimenopausal female or a male, AND b. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist OR had surgical bilateral oophorectomy or ovarian irradiation (female) or orchiectomy (male), Note: Examples of a GnRH agonist include leuprolide acetate, leuprolide acetate intramuscular injection, triptorelin pamoate intramuscular injection, goserelin acetate subcutaneous injection. AND B. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease, AND C. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D. Patient has PIK3CA-mutated breast cancer as detected by an approved test, AND E. Patient meets (i or ii): i) has disease progression while on adjuvant endocrine therapy or ii) had disease recurrence within 12 months after completing adjuvant endocrine therapy, Note: Examples of endocrine therapy include tamoxifen, anastrozole, letrozole, exemestane, toremifene. AND F. The medication will be used in combination with palbociclib capsules/tablets and fulvestrant injection. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ITRACONAZOLE

**Products Affected**

- itraconazole oral capsule

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | The requested drug will be used orally. For the treatment of onychomycosis due to dermatophytes (Tinea unguium), the diagnosis has been confirmed by a fungal diagnostic test (e.g., potassium hydroxide [KOH] preparation, fungal culture, or nail biopsy). For primary treatment of allergic bronchopulmonary aspergillosis, the requested drug is initiated in combination with systemic corticosteroids. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Disseminated/CNS histo, histo/CM/CGD ppx, chronic cavitary/necrotizing PA: 12 mths. Others: 6 mths |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# IVERMECTIN (ORAL)

**Products Affected**

- ivermectin oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | Pediculosis-approve if the patient has infection caused by pediculus humanus capitis (head lice), pediculus humanus corporis (body lice), or has pediculosis pubis caused by phthirus pubis (pubic lice). Scabies-approve if the patient has classic scabies, treatment resistant scabies, is unable to tolerate topical treatment, has crusted scabies or is using ivermectin tablets for prevention and/or control of scabies. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Ascariasis, Enterobiasis (pinworm infection), Hookworm-related cutaneous larva migrans, Mansonella ozzardi infection, Mansonella streptocerca infection, Pediculosis, Scabies. Trichuriasis, Wucheria bancrofti infection |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# IVIG

**Products Affected**

- Gamunex-C injection solution 1 gram/10 mL (10 %)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# IWILFIN

**Products Affected**

- Iwilfin

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Neuroblastoma-Approve if the patient meets the following (A, B and C): A) Patient has high-risk disease, AND B) The medication is being used to reduce the risk of relapse, AND C) Patient has had at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy. Note: Examples of anti-GD2 immunotherapy includes Unituxin (dinutuximab intravenous infusion). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# JAKAFI

**Products Affected**

- Jakafi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | ALL-1 to 21 years of age, GVHD-12 and older, MF/PV/accelerated or blast phase MPN/CMML-2/essential thrombo/myeloid/lymphoid neoplasm/T-cell Lymphoma-18 and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | For polycythemia vera patients must have tried hydroxyurea or peginterferon alfa-2a or Besremi (ropeginterferon alfa-2b-njft subcutaneous injection). ALL-approve if the mutation/pathway is Janus associated kinase (JAK)-related. GVHD, chronic-approve if the patient has tried one conventional systemic treatment for graft versus host disease (for example: prednisone, ibrutinib capsules/tablets). GVHD, acute-approve if the patient has tried one systemic corticosteroid. Atypical chronic myeloid leukemia-approve if the patient has a CSF3R mutation or a janus associated kinase 2 (JAK2) mutation. Chronic monomyelocytic leukemia-2 (CMML-2)-approve if the patient is also receiving a hypomethylating agent. Essential thrombocythemia-approve if the patient has tried hydroxyurea, peginterferon alfa-2a or anagrelide. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the tumor has a janus associated kinase 2 (JAK2) rearrangement. T-Cell Lymphoma - approve if pt has (A or B): A) peripheral T-cell lymphoma or B) meets (i and ii): i) pt has T-cell prolymphocytic leukemia, T-cell large granular lymphocytic leukemia, hepatosplenic T-cell lymphoma, or breast implant-associated anaplastic large cell lymphoma and ii) pt has tried at least one systemic regimen. Accelerated or blast phase myeloproliferative neoplasm-approve if pt has at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Acute lymphoblastic leukemia, atypical chronic myeloid leukemia, chronic monomyelocytic leukemia-2 (CMML-2), essential thrombocythemia, myeloid/lymphoid neoplasms, T-Cell lymphoma, accelerated or blast phase myeloproliferative neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# JAYPIRCA

**Products Affected**

- Jaypirca

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Mantle cell lymphoma-approve if the patient has tried at least one systemic chemotherapy regimen or patient is not a candidate for a systemic regimen (i.e., an elderly patient who is frail), AND the patient has tried one Bruton tyrosine kinase inhibitor (BTK) for mantle cell lymphoma.Note: Examples of a systemic regimen contain one or more of the following products: rituximab, cytarabine, carboplatin, cisplastin, oxaliplatin, cyclophosphamide, doxorubicin, vincristine, methotrexate, bendamustine, Velcade (bortezomib intravenous or subcutaneous injection), lenalidomide, gemcitabine, and Venclexta (venetoclax tablets). Note: Examples of BTK inhibitors indicated for mantle cell lymphoma include Brukinsa (zanubrutinib capsules), Calquence (acalabrutinib capsules), and Imbruvica (ibrutinib capsules, tablets, and oral suspension). CLL/SLL-patient meets (A or B): A) patient has resistance or intolerance to Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules) or B) patient has relapsed or refractory disease and has tried a Bruton tyrosine kinase (BTK) inhibitor and Venclexta (venetoclax tablet)-based regimen. Examples of BTK inhibitor include: Imbruvica (ibrutinib tablets, capsules, or oral solution), Calquence (acalabrutinib tablets), or Brukinsa (zanubrutinib capsules). Richter's Transformation to DLBCL- pt has tried at least one chemotherapy regimen or is not a candidate for a chemotherapy regimen. Marginal Zone Lymphoma - approve if pt has tried at least one Bruton tyrosine kinase inhibitor. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Richter's Transformation to Diffuse Large B-Cell Lymphoma, Marginal Zone Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# JYNARQUE

**Products Affected**

- Jynarque oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD |
| **Required Medical Information** | Diagnosis, renal function |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a nephrologist |
| **Coverage Duration** | 1 year (initial and continuation) |
| **Other Criteria** | Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# KETOCONAZOLE

**Products Affected**

- ketoconazole oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Acute or chronic liver disease. Concurrent use with drugs that are contraindicated with ketoconazole tablets: dofetilide, quinidine, pimozide, cisapride, methadone, disopyramide, dronedarone, ranolazine, ergot alkaloids, irinotecan, lurasidone, oral midazolam, alprazolam, triazolam, felodipine, nisoldipine, tolvaptan, eplerenone, lovastatin, simvastatin, or colchicine. |
| **Required Medical Information** | The potential benefits outweigh the risks of treatment with oral ketoconazole. For systemic fungal infections, the patient has any of the following diagnoses: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis. For Cushing's syndrome: the requested drug is being prescribed for a patient who cannot tolerate surgery or where surgery has not been curative. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Cushing's syndrome |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# KINERET

**Products Affected**

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another biologic DMARD or targeted synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | RA/AOSD-18 years and older, SJIA-2 years and older |
| **Prescriber Restrictions** | Initial therapy only-RA, SJIA and Still's disease, prescribed by or in consultation with a rheumatologist. CAPS (Neonatal-Onset Multisystem Inflammatory Disease or Chronic Infantile Neurological Cutaneous and Articular [CINCA] syndrome), prescribed by or in consultation with a rheumatologist, geneticist, allergist/immunologist, or dermatologist.DIRA-rheum, geneticist, dermatologist, or physician specializing in the treatment of autoinflammatory disorder. |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | RA initial. Approve if the patient has tried TWO of the following drugs in the past: Enbrel, a preferred adalimumab product, Rinvoq, Xeljanz/XR, or a preferred tocilizumab product. [Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: a non-preferred tocilizumab product, Orencia, Cimzia, infliximab, Kevzara, golimumab IV/SC or another non-preferred adalimumab product.] DIRA initial-approve if genetic testing has confirmed bi-allelic pathogenic variants in the IL1RN gene. Adult Onset Still's Disease, approve. SJIA-initial-approve. cont tx - approve if the patient had responded to therapy as determined by the prescriber. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Adult onset Still's disease (SD). Systemic Juvenile Idiopathic Arthritis (SJIA) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# KISQALI

**Products Affected**

- Kisqali

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast cancer - approve for hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative early (stage II or III), recurrent, or metastatic breast cancer [for early breast cancer must be adjuvant treatment and high risk of recurrence] when the pt meets ONE of the following (1, 2, 3 or 4): 1. Pt is postmenopausal and Kisqali will be used in combination with anastrozole, exemestane, or letrozole 2. meets (a, b and c): a) pt is premenopausal or perimenopausal and b) is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND c) Kisqali will be used in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH analog AND Kisqali with be used in combination with anastrozole, exemestane or letrozole. 4. Patient meets (a and b): a) is postmenopausal, pre/perimenopausal (patient receiving ovarian suppression/ablation with a GnRH agonist or has had surgical bilateral oophorectomy or ovarian irradiation) or a man, and b) Kisqali will be used in combination with fulvestrant. Endometrial cancer - approve if pt meets all of (A, B and C): A) pt has recurrent or metastatic disease, and B) has estrogen receptor (ER)-positive tumors, and C) if request is for Kisqali, Kisqali will be used in combination with letrozole. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Endometrial cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# KORLYM

**Products Affected**

- mifepristone oral tablet 300 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# KOSELUGO

**Products Affected**

- Koselugo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Neurofibromatosis Type 1-approve if prior to starting Koselugo, the patient has symptomatic, inoperable plexiform neurofibromas and if the patient is 2 to 18 years old OR if the patient is 19 years or older if the patient started on therapy with Koselugo prior to becoming 19. Circumscribed Glioma-approve if the patient has recurrent, refractory or progressive disease AND the tumor is BRAF fusion positive OR BRAF V600E activating mutation positive OR patient has neurofibromatosis type 1 mutated glioma AND this medication will be used as a single agent AND the patient is 3-21 years of age OR is greater 21 and has been previously started on therapy with Koselugo prior to becoming 21 years of age. Langerhans Cell Histiocytosis- approve if the patient meets the following criteria (A and B): A) Patient meets one of the following (i, ii, iii, iv, or v): i. Patient meets both of the following (a and b): a) Patient has multisystem Langerhans cell histiocytosis, AND b) Patient has symptomatic disease or impending organ dysfunction, OR ii. Patient has single system lung Langerhans cell histiocytosis, OR iii. Patient meets (a and b): a) Patient has single system bone disease, AND b) Patient has not responded to treatment with a bisphosphonate, OR iv. Patient has central nervous system disease, OR v. patient has relapsed or refractory disease, AND B) The medication is used as a single agent. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Circumscribed Glioma, Langerhans Cell Histiocytosis |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# KRAZATI

**Products Affected**

- Krazati

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-approve if (A and B): A) the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an approved test AND B) patient meets either (i or ii): i) has been previously treated with at least one systemic regimen [Examples of systemic regimens include those containing one or more of the following products: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Tecentriq (atezolizumab intravenous infusion), Alimta (pemetrexed intravenous infusion), Yervoy (ipilimumab intravenous infusion), Abraxane (albumin-bound paclitaxel intravenous infusion), bevacizumab, cisplatin, carboplatin, docetaxel, gemcitabine, paclitaxel, vinorelbine.] or ii) patient has brain metastases. Colon or Rectal Cancer- approve if pt has unresectable, advanced, or metastatic disease AND pt has KRAS G12C mutation-positive disease AND medication is prescribed as part of a combination regimen or the patient is unable to tolerate combination therapy AND pt has has previously received a chemotherapy regimen for colon or rectal cancer. Ampullary adenocarcinoma-approve if (A, B and C): A) metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. Biliary tract cancer- approve if (A, B and C): A) unresectable or metastatic disease, B) KRAS G12C mutation-positive disease, and C) previously treated with at least one systemic regimen. Pancreatic adenocarcinoma- approve if (A and B): A) KRAS G12C mutation-positive disease, and B) either (i or ii): (i) locally advanced or metastatic disease and previously treated with at least one systemic regimen, or (ii) recurrent disease after resection. Small bowel adenocarcinoma- approve if (A, B and C): A) advanced or metastatic disease, B) KRAS G12C mutation-positive disease, and C) will be used as subsequent therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Ampullary adenocarcinoma, biliary tract cancer, pancreatic adenocarcinoma, small bowel adenocarcinoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LAPATINIB

**Products Affected**

- lapatinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# LAZCLUZE

**Products Affected**

- Lazcluze

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NON-SMALL CELL LUNG CANCER-ALL of the following (A, B, C, and D): A. Locally advanced or metastatic disease, AND B. Epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test, AND C. Used in combination with Rybrevant, AND D. Used as first-line treatment. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# LEDIPASVIR/SOFOSBUVIR

**Products Affected**

- ledipasvir-sofosbuvir

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Indications consistent with current AASLD/IDSA guidance |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# LENALIDOMIDE

**Products Affected**

- lenalidomide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older (except Kaposi Sarcoma, Castleman Disease, Primary CNS Lymphoma) |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Follicular lymphoma-approve if (A, B or C): A) the patient is using lenalidomide in combination with rituximab or B) using in combination with Gazyva (obinutuzumab intravenous infusion), or C) pt has tried at least one prior therapy. MCL-approve -if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. MZL-approve if the patient is using lenalidomide in combination with rituximab or has tried at least one other regimen. Multiple myeloma-approve. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]), OR 4) meets (i, ii and iii): i) pt has myelodysplastic syndrome/myeloproliferative neoplasm overlap neoplasm, and ii) has SF3B1 mutation, and iii) pt has thrombocytosis . B-cell-lymphoma (other) [examples: diffuse large B-cell lymphoma, high grade B-cell lymphoma, post-transplant lymphoproliferative disorders, HIV-related B-cell lymphoma]-approve if the pt has tried at least one prior therapy. Myelofibrosis-approve if according to the prescriber the patient has anemia with presence of del(5q) and will use this in combination with prednisone. Primary CNS lymphoma-approve if according to the prescriber the patient has relapsed or refractory disease, or is not a candidate for high-dose MTX, or had intolerance to high-dose MTX. Hodgkin lymphoma, classic-approve if (A and B): A) pt has relapsed or refractory disease, and B) pt is not a candidate for high-dose therapy and autologous stem cell rescue. Castleman disease-approve if the patient has relapsed/refractory or progressive disease. Kaposi Sarcoma-approve if the patient has tried at least one regimen or therapy and the patient has relapsed or refractory disease. Systemic light chain amyloidosis-approve if lenalidomide is used in combination with dexamethasone. Histiocytic neoplasms-approve if (A or B): A) the patient has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has Rosai-Dorfman disease. T-Cell lymphoma- approve if (A, B or C): A) pt has peripheral T-cell lymphoma, or B) pt has T-cell leukemia/lymphoma and has tried at least one other regimen, or C) pt has hepatosplenic T-cell lymphoma and has tried at least two other regimens. Chronic lymphocytic leukemia/Small lymphocytic leukemia-approve if (A, B and C): A) relapsed or refractory disease, and B) tried at least |
| | one Bruton-tyrosine kinase inhibitor, and C) tried at least one B-cell lymphoma (BCL)2 inhibitor. POEMS Syndrome- approve if used in combination with dexamethasone. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Systemic Amyloidosis Light Chain, B-Cell Lymphoma (other), Myelofibrosis, Castleman Disease, Hodgkin lymphoma (Classic), T-Cell Lymphoma, Primary Central nervous system Lymphoma, Kaposi sarcoma, histiocytic neoplasms, Chronic Lymphocytic Leukemia, Small Lymphocytic Leukemia, POEMS syndrome. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LENVIMA

**Products Affected**

- Lenvima

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ALL of the following criteria: 1) pt has advanced disease AND if the patient meets i or ii-i. Lenvima is is being used in combination with Keytruda OR ii. Lenvima is used in combination with Afinitor/Afinitor Disperz and the patient meets a or b-a. Patient has clear cell histology and patient has tried one antiangiogenic therapy or b. patient has non-clear cell histology. MTC-approve if the patient has tried at least one systemic therapy. Endometrial Carcinoma-Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has advanced endometrial carcinoma that is mismatch repair proficient (pMMR) or not microsatellite instability-high (MSI-H) AND B) The medication is used in combination with Keytruda (pembrolizumab for intravenous injection) AND C)the disease has progressed on at least one prior systemic therapy AND D) The patient is not a candidate for curative surgery or radiation. HCC-approve if the patient has unresectable or metastatic disease. Thymic carcinoma-approve if the patient has tried at least one chemotherapy regimen. Melanoma - approve if the patient has unresectable or metastatic melanoma AND the medication will be used in combination with Keytruda (pembrolizumab intravenous injection) AND the patient has disease progression on anti-programmed death receptor-1 (PD-1)/programmed death-ligand 1 (PD-L1)-based therapy. Anaplastic thyroid carcinoma-approve if the medication is used in combination with Keytruda (pembrolizumab intravenous infusion). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Patients with Medullary Thyroid Carcinoma (MTC), thymic carcinoma, Melanoma, Anaplastic thyroid carcinoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LIDOCAINE PATCH

**Products Affected**

- lidocaine topical adhesive patch,medicated 5 %
- Lidocan III
- Tridacaine II

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Diabetic neuropathic pain, chronic back pain |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# LIVTENCITY

**Products Affected**

- Livtencity

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with ganciclovir or valganciclovir |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 12 years and older (initial therapy) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist, infectious diseases specialist, oncologist, or a physician affiliated with a transplant center. (initial therapy) |
| **Coverage Duration** | 2 months |
| **Other Criteria** | Cytomegalovirus Infection, Treatment, initial therapy-approve if the patient meets the following criteria (A, B, and C): A) Patient weighs greater than or equal to 35 kg, AND B) Patient is post-transplant, AND Note: This includes patients who are post hematopoietic stem cell transplant or solid organ transplant. C) Patient has cytomegalovirus infection/disease that is refractory to treatment with at least one of the following: cidofovir, foscarnet, ganciclovir, or valganciclovir or patient has a significant intolerance to ganciclovir or valganciclovir. Cytomegalovirus Infection, Treatment, continuation of therapy - approve if patient has responded as demonstrated by cytomegalovirus polymerase chain DNA laboratory results within 4 weeks demonstrating improvement in cytomegalovirus levels. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LONG ACTING OPIOIDS

**Products Affected**

- methadone oral solution
- methadone oral tablet
- morphine oral tablet extended release

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Acute (ie, non-chronic) pain |
| **Required Medical Information** | Pain type (chronic vs acute), prior pain medications/therapies tried, concurrent pain medications/therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | For pain severe enough to require daily, around-the-clock, long-term opioid treatment, approve if all of the following criteria are met: 1) patient is not opioid naive, AND 2) non-opioid therapies have been tried and are being used in conjunction with opioid therapy according to the prescribing physician, AND 3) the prescribing physician has checked the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP), AND 4) the prescribing physician has discussed risks (eg, addiction, overdose) and realistic benefits of opioid therapy with the patient, AND 5) according to the prescriber physician there is a treatment plan (including goals for pain and function) in place and reassessments are scheduled at regular intervals. Patients with cancer, in hospice, sickle cell disease or who reside in a long term care facility are not required to meet above criteria. Clinical criteria incorporated into the quantity limit edits for all oral long-acting opioids require confirmation that the indication is intractable pain (ie, FDA labeled use) prior to reviewing for quantity exception. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# LONSURF

**Products Affected**

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Colon, rectal or appendiceal cancer- approve if patients meets (A, B, and C): A) advanced or metastatic disease, B) meets (i or ii): i) has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease or ii) is ineligible for or progressed on checkpoint inhibitor therapy and meets ONE of the following (a or b): a) has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease, or b) is polymerase epsilon/delta (POLE/POLD1) mutation positive, and C) has previously been treated with ALL of the following per labeling (i, ii and iii): i) fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, ii) an anti-vascular endothelial growth factor (VEGF) agent (ex: bevacizumab), and iii) if the tumor is wild-type RAS (KRAS wild-type and NRAS wild-type), patient has received anti-EGFR therapy (ex: Erbitux or Vectibix) or EGFR therapy is not medically appropriate. Gastric or Gastroesophageal Junction Adenocarcinoma, approve if the patient has been previously treated with at least two chemotherapy regimens for gastric or gastroesophageal junction adenocarcinoma. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Appendiceal cancer |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# LORBRENA

**Products Affected**

- Lorbrena

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Pediatric Diffuse High-Grade Glioma- less than 18 years old, All others- 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Erdheim Chester disease-approve if the patient has anaplastic lymphoma kinase (ALK) rearrangement/fusion-positive disease. Inflammatory myofibroblastic tumor (IMT)-approve if the patient has ALK-positive disease and (i or ii): i) advanced, recurrent, or metastatic disease or ii) tumor is inoperable. NSCLC - Approve if the patient has ALK-positive advanced or metastatic NSCLC, as detected by an approved test. NSCLC-ROS1 Rearrangement-Positive, advanced or metastatic NSCLC-approve if the patient has tried at least one of crizotinib, entrectinib or ceritinib. Large B-Cell Lymphoma- approve if ALK-positive disease and disease is relapsed or refractory. Pediatric Diffuse High-Grade Glioma-approve if ALK-positive disease and (i or ii): i) used as adjuvant therapy, or ii) used for recurrent or progressive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Non-small cell lung cancer (NSCLC)-ROS1 Rearrangement-Positive, Erdheim Chester Disease, Inflammatory Myofibroblastic Tumor (IMT), Large B-Cell Lymphoma, Pediatric Diffuse High-Grade Glioma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LUMAKRAS

**Products Affected**

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-approve if the patient has KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test AND has been previously treated with at least one systemic regimen. Ampullary adenocarcinoma - approve if pt has KRAS G12C-mutated disease as determined by an approved test AND this is used as subsequent therapy. Colon or rectal cancer - approve if pt meets all (A, B, C and D): A) advanced or metastatic disease, and B) KRAS G12C mutation-positive disease, and C) used in combination with Erbitux (cetuximab intravenous infusion) or Vectibix (panitumumab intravenous infusion) or patient is unable to tolerate combination therapy, and D) previously received a chemotherapy regimen for colon or rectal cancer. Pancreatic Adenocarcinoma- approve if patient has KRAS G12C-mutated disease, as determined by an approved test AND either (i or ii): (i) patient has locally advanced or metastatic disease and has been previously treated with at least one systemic regimen OR (ii) patient has recurrent disease after resection. Small bowel adenocarcinoma- approve if pt meets all of (A, B and C): A) has advanced or metastatic disease, and B) has KRAS G12C mutation-positive disease, and C) medication will be used as subsequent therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Pancreatic Adenocarcinoma, Ampullary Adenocarcinoma, Small Bowel Adenocarcinoma |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LUPRON DEPOT

**Products Affected**

- Lupron Depot

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Premenstrual disorders - 18 years and older |
| **Prescriber Restrictions** | Prostate cancer-prescribed by/consultation with oncologist or urologist. Other cancer diagnosis- prescribed by/consultation with an oncologist. Gender dysphoria/reassignment- prescribed by/consultation with endocrinologist or physician who specializes in treatment of transgender patients |
| **Coverage Duration** | uterine leiomyomata - 3 months, abnormal uterine bleeding - 6 months, all others - 12 months |
| **Other Criteria** | Endometriosis-approve if the pt has tried one of the following, unless contraindicated: a contraceptive, an oral progesterone or depo-medroxyprogesterone injection. An exception can be made if the pt has previously tried a gonadotropin-releasing hormone [GnRH] agonist (e.g. Lupron Depot) or antagonist (e.g. Orilissa). Head and neck cancer-salivary gland tumor-approve if pt has recurrent, unresectable, or metastatic disease AND androgen receptor-positive disease. Premenstrual disorders including PMS and PMDD-approve if pt has severe refractory premenstrual symptoms AND pt has tried an SSRI or combined oral contraceptive. Prostate cancer - for patients new to therapy requesting Lupron Depot 7.5mg, patients are required to try Eligard prior to approval. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Abnormal uterine bleeding, breast cancer, gender dysphoria/gender reassignment, head and neck cancer-salivary gland tumors, ovarian cancer including fallopian tube and primary peritoneal cancers, premenstrual disorders including premenstrual syndrome and premenstrual dysphoric disorder, prophylaxis or treatment of uterine bleeding or menstrual suppression in pts with hematologic malignancy or undergoing cancer treatment or prior to bone marrow or stem cell transplant, uterine cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LYNPARZA

**Products Affected**

- Lynparza

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Ovarian, Fallopian Tube, or Primary Peritoneal Cancer - Maintenance monotherapy-Approve if the patient has a germline or somatic BRCA mutation-positive disease as confirmed by an approved test AND The patient is in complete or partial response to at least one platinum-based chemotherapy regimen (e.g., carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine). Ovarian, fallopian tube, or primary peritoneal cancer-maintenance, combination therapy-approve if the medication is used in combination with bevacizumab, the patient has homologous recombination deficiency (HRD)-positive disease, as confirmed by an approved test and the patient is in complete or partial response to first-line platinum-based chemotherapy regimen. Breast cancer, adjuvant-approve if the patient has germline BRCA mutation-positive, HER2-negative breast cancer and the patient has tried neoadjuvant or adjuvant therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has recurrent or metastatic disease and has (i or ii): i) germline BRCA mutation-positive breast cancer or ii) germline PALB2 mutation-positive breast cancer. Pancreatic Cancer-maintenance therapy-approve if the patient has a germline BRCA mutation-positive metastatic disease and the disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen. Prostate cancer-castration resistant-approve if the patient has metastatic disease, the medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog or the pateint has had a bilateral orchiectomy, and the patient meets either (i or ii): i) the patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test and the patient has been previously treated with at least one androgen receptor directed therapy or ii) the patient has a BRCA mutation and the medication is used in combination with abiraterone plus one of prednisone or prednisolone. Uterine Leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Uterine Leiomyosarcoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# LYTGOBI

**Products Affected**

- Lytgobi oral tablet 12 mg/day (4 mg x 3), 16 mg/day (4 mg x 4), 20 mg/day (4 mg x 5)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cholangiocarcinoma-approve if the patient has unresectable locally advanced or metastatic disease, tumor has fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements as detected by an approved test and if the patient has been previously treated with at least one systemic regimen. Note: Examples of systemic regimens include gemcitabine + cisplatin, 5-fluorouracil + oxaliplatin or cisplatin, capecitabine + cisplatin or oxaliplatin, gemcitabine + Abraxane (albumin-bound paclitaxel) or capecitabine or oxaliplatin, and gemcitabine + cisplatin + Abraxane. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# MEGESTROL

**Products Affected**

- megestrol oral suspension 400 mg/10 mL (40 mg/mL), 625 mg/5 mL (125 mg/mL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for weight gain for cosmetic reasons. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 12 months |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# MEKINIST

**Products Affected**

- Mekinist

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 1 year and older (low grade glioma/solid tumors) |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Melanoma (not including uveal melanoma)- must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. Uveal melanoma - approve if metastatic or unresectable disease. For NSCLC - approve if (A, B and C): A) recurrent, advanced or metastatic disease and B) pt has BRAF V600 Mutation and C) pt will use in combination with Tafinlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafinlar AND the patient has BRAF V600-positive disease. Ovarian/fallopian tube/primary peritoneal cancer-approve if the patient has recurrent disease and the medication is used for (a or b): a) low-grade serous carcinoma or b) the patient has BRAF V600 mutation positive disease and the medication will be taken in combination with Tafinlar. Low grade glioma-patient has BRAF V600 mutation positive disease and the medication will be used in combination with Tafinlar. Histiocytic neoplasm-approve if patient has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. Solid Tumors [Note: Examples of solid tumors are: biliary tract cancer, brain metastases due to melanoma, high-grade gliomas, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, pancreatic adenocarcinoma, neuroendocrine tumors, occult primary, and ampullary adenocarcinoma]- Approve if the patient meets the following (A and B): A) Patient has BRAF V600 mutation-positive disease, AND B) The medication will be taken in combination with Tafinlar (dabrafenib capsules). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Tafinlar. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Tafinlar AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Histiocytic Neoplasm, Hairy Cell Leukemia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# MEKTOVI

**Products Affected**

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, BRAF V600 status, concomitant medications |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Histiocytic neoplasm-approve if the patient has Langerhans cell histiocytosis and one of the following (i, ii, or iii): i. multisystem disease OR, ii. pulmonary disease or, iii. central nervous system lesions. NSCLC-approve if pt has BRAF V600E mutation-positive metastatic disease AND this medication will be taken in combination with Braftovi (encorafenib capsules). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Histiocytic Neoplasms |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# MEMANTINE

**Products Affected**

- memantine oral capsule,sprinkle,ER 24hr
- memantine oral solution
- memantine oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Indication for which memantine is being prescribed. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | This Prior Authorization requirement only applies to patients 26 years of age or younger |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Patients with mild to moderate vascular dementia. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# MODAFINIL/ARMODAFINIL

**Products Affected**

- armodafinil
- modafinil

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NAYZILAM

**Products Affected**

- Nayzilam

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other medications used at the same time |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NERLYNX

**Products Affected**

- Nerlynx

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Stage of cancer, HER2 status, previous or current medications tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Adjuvant tx-Approve for 1 year (total), advanced or metastatic disease-1 year |
| **Other Criteria** | Breast cancer, adjuvant therapy - approve if the patient meets all of the following criteria: patient will not be using this medication in combination with HER2 antagonists, patient has HER2-positive breast cancer AND Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. Breast cancer, recurrent or metastatic disease-approve if the patient has HER-2 positive breast cancer, Nerlynx will be used in combination with capecitabine and the patient has tried at least two prior anti-HER2 based regimens. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NEXLETOL

**Products Affected**

- Nexletol

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field) |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL, b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, AND B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and ezetimibe and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and ezetimibe and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD or HeFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NILOTINIB

**Products Affected**

- Danziten
- Tasigna

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | GIST/Myeloid/lymphoid neoplasms/melanoma, cutaneous-18 years and older, ALL - 15 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Acute lymphoblastic leukemia, philadelphia chromosome positive-approve. CML, philadelphia chromosome positive or BCR::ABL1-mutation positive chronic myeloid leukemia- approve. For GIST, approve if the patient has tried two of the following: imatinib, avapritinib, sunitinib, dasatinib, regorafinib or ripretinib. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an ABL1 rearrangement. Pigmented villonodular synovitis/tenosynovial giant cell tumor-approve if the patient has tried Turalio or Romvimza or cannot take Turalio or Romvimza, according to the prescriber. For melanoma, cutaneous - approve if the patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST), Pigmented villonodular synovitis/tenosynovial giant cell tumor, Myeloid/Lymphoid neoplasms with Eosinophilia, melanoma cutaneous. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NINLARO

**Products Affected**

- Ninlaro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | MM - approve if (A, B, C or D): A) this medication will be used in combination with lenalidomide or cyclophosphamide and dexamethasone, OR B) pt had received at least ONE prior regimen for multiple myeloma OR C) this medication will be used following hematopoietic stem cell transplantation or D) the patient is not a candidate for bortezomib or Kyprolis (carfilzomib intravenous infusion) and is also not a transplant candidate. Systemic light chain amyloidosis-approve if the patient has tried at least one other regimen for this condition. Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma-approve if used in combination with a rituximab product and dexamethasone (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Patients with systemic light chain amyloidosis, Waldenstrom Macroglobulinemia/lymphoplasmacytic lymphoma, Multiple myeloma after previous treatment (either monotherapy or in combination other than lenalidomide/dexamethasone) or stem cell transplant |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# NITISINONE

**Products Affected**

- nitisinone

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant therapy with nitisinone products |
| **Required Medical Information** | Diagnosis, genetic tests and lab results (as specified in the Other Criteria field) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases) |
| **Coverage Duration** | 1 year |
| **Other Criteria** | HereditaryTyrosinemia, Type 1-approve if the prescriber confirms the diagnosis was confirmed by genetic testing confirming biallelic pathogenic/likely pathogenic variants in the FAH gene OR elevated levels of succinylacetone in the serum or urine. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NIVESTYM

**Products Affected**

- Nivestym

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Cancer/AML, MDS, ALL-oncologist or a hematologist. Cancer patients receiving BMT and PBPC-prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. Radiation-expertise in acute radiation. SCN-hematologist. HIV/AIDS neutropenia-infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS. |
| **Coverage Duration** | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,ALL,BMT, Radiation-1 mo |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: 1)patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2)patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status, or HIV infection patients with low CD4 counts), 3)patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment, or 4)patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm3], neutropenia expected to be greater than 10 days in duration, pneumonia or other clinically documented infections, invasive fungal infection, hospitalization at the time of fever, prior episode of febrile neutropenia). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Acute lymphocytic leukemia (ALL), Radiation Syndrome (Hematopoietic Syndrome of Acute Radiation Syndrome) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NON-INJECTABLE TESTOSTERONE PRODUCTS

**Products Affected**

- testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %), 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients. |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization)-approve.Note: For a patient who has undergone gender reassignment, use this FTM criterion for hypogonadism indication. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Gender-Dysphoric/Gender-Incongruent Persons, Persons Undergoing Female-to-Male (FTM) Gender Reassignment (i.e., Endocrinologic Masculinization) |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NUBEQA

**Products Affected**

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (See Note 1) or if the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration sensitive-approve if the medication will be used in combination with a GnRH analog (See Note 1) or if the patient had a bilateral orchiectomy. Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NUEDEXTA

**Products Affected**

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NUPLAZID

**Products Affected**

- Nuplazid

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# NURTEC

**Products Affected**

- Nurtec ODT

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with another calcitonin gene-related peptide (CGRP) inhibitor being prescribed for migraine headache prevention if Nurtec ODT is being taking for the preventive treatment of episodic migraine. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Migraine, Acute treatment-approve if the patient has tried at least one triptan or has a contraindication to triptans. Preventive treatment of episodic migraine-approve if the patient has greater than or equal to 4 but less than 15 migraine headache days per month (prior to initiating a migraine preventive medication) and if the patient is currently taking Nurtec ODT, the patient has had a significant clinical benefit from the medication. Examples of significant clinical benefit include a reduction in the overall number of migraine days per month or a reduction in number of severe migraine days per month from the time that Nurtec ODT was initiated. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# NYVEPRIA

**Products Affected**

- Nyvepria

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Cancer patients receiving chemotherapy-prescribed by or in consultation with an oncologist or hematologist. PBPC-prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. |
| **Coverage Duration** | Cancer pts receiving chemo-6 mo. PBPC-1 mo |
| **Other Criteria** | Cancer patients receiving chemotherapy, approve if the patient meets one of the following: 1) is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), 2) patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (eg, aged greater than 65 years receiving full chemotherapy dose intensity, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver dysfunction (bilirubin greater than 2 mg/dL), renal dysfunction (CrCl less than 50 mL/min), poor performance status or HIV infection patients with low CD4 counts), or 3) patient has had a neutropenic complication from prior chemotherapy cycle and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Patients undergoing PBPC collection and therapy |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# OCTREOTIDE INJECTABLE

**Products Affected**

- octreotide acetate injection solution

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Acromegaly-prescr/consult w/endocrinologist. NETs-prescr/consult w/oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescr/consult w/endo/onc/neuro.Meningioma-prescr/consult w/oncologist, radiologist, neurosurg/thymoma/thymic carcinoma-presc/consult with oncologist. Diarrhea assoc w chemo-presc/consult with oncologist/gastro. |
| **Coverage Duration** | Enterocutaneous fistula/diarrhea asssoc w chemo - 3 months, all others - 1 year |
| **Other Criteria** | ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. DIARRHEA ASSOC W CHEMO (A and B): A) grade 3 or 4 diarrhea [Examples: more than 6 bowel movements above baseline per day, colitis symptoms, interference with activities of daily living, hemodynamic instability, hospitalization, serious complications (eg, ischemic bowel, perforation, toxic mega-colon), or other colitis-related life-threatening conditions] and B) patient has tried at least one antimotility medication. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Meningioma, thymoma and thymic carcinoma, pheochromocytoma and paraganglioma, enterocutaneous fistulas, diarrhea associated with chemotherapy |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# ODOMZO

**Products Affected**

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# OFEV

**Products Affected**

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | IDIOPATHIC PULMONARY FIBROSIS (IPF), INITIAL [A and B]: A) diagnosis confirmed by presence of usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) or surgical lung biopsy and B) forced vital capacity (FVC) greater than or equal to 40 percent of the predicted value. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS, INITIAL (A and B): A) diagnosis confirmed by HRCT and B) FVC greater than or equal to 40 percent of the predicted value. CHRONIC FIBROSING INTERSTITIAL LUNG DISEASE, INITIAL (all of A, B and C): A) FVC greater than or equal to 45 percent of the predicted value, B) fibrosing lung disease impacting more than 10 percent of lung volume on HRCT, and C) clinical signs of progression. ALL INDICATIONS, CONTINUATION: approve. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# OGSIVEO

**Products Affected**

- Ogsiveo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Desmoid tumors (aggressive fibromatosis)-approve if the patient has progressing desmoid tumors, the desmoid tumors are not amenable to surgery or radiotherapy and if the patient requires systemic treatment. Note: Progressing desmoid tumors are defined as greater than or equal to 20 percent progression within 12 months |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# OJEMDA

**Products Affected**

- Ojemda

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 6 months of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | PEDIATRIC LOW GRADE GLIOMA-patient has relapsed or refractory disease and the tumor is positive for one of the following: BRAF fusion, BRAF rearrangement or BRAF V600 mutation. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# OJJAARA

**Products Affected**

- Ojjaara

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis-approve if the patient has (A, B or C): A) higher-risk disease, or B) lower-risk disease and has one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis), or C) myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease- related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Accelerated or blast phase myeloproliferative neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ONUREG

**Products Affected**

- Onureg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML - Approve if the medication is used for post-remission maintenance therapy AND allogeneic hematopoietic stem cell transplant is not planned. Peripheral T-cell lymphoma - all of (A, B, and C): A) relapsed or refractory disease, and B) pt has one of the following (i, ii or iii): i) angioimmunoblastic T-cell lymphoma, or ii) nodal peripheral T-cell lymphoma with T-follicular helper (TFH) phenotype, or iii) follicular T-cell lymphoma, and C) medication is used as a single agent. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Peripheral T-cell lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ORGOVYX

**Products Affected**

- Orgovyx

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Prostate Cancer-approve. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ORSERDU

**Products Affected**

- Orserdu

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast cancer in postmenopausal women or Men-approve if the patient meets the following criteria (A, B, C, D, and E): A) Patient has recurrent or metastatic disease, AND B) Patient has estrogen receptor positive (ER+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has estrogen receptor 1 gene (ESR1)-mutated disease, AND E) Patient has tried at least one endocrine therapy. Note: Examples of endocrine therapy include fulvestrant, anastrozole, exemestane, letrozole, and tamoxifen. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# OTEZLA

**Products Affected**

- Otezla
- Otezla Starter oral tablets,dose pack 10 mg (4)-20 mg (51), 10 mg (4)-20 mg (4)-30 mg (47)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# OXERVATE

**Products Affected**

- Oxervate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment duration greater than 16 weeks per affected eye(s) |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by an ophthalmologist or an optometrist. |
| **Coverage Duration** | Initial-8 weeks, continuation-approve for an additional 8 weeks |
| **Other Criteria** | Patient has Stage 2 or higher neurotrophic keratitis. Patients who have already received Oxervate-approve if the patient has previously received less than or equal to 8 weeks of treatment per affected eye(s) and the patient has a recurrence of neurotrophic keratitis. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PANRETIN

**Products Affected**

- Panretin

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a dermatologist, oncologist, or infectious disease specialist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Kaposi Sarcoma-approve if the patient is not receiving systemic therapy for Kaposi Sarcoma. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PEGASYS

**Products Affected**

- Pegasys

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | HBV 48wks. Other Plan Yr |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloproliferative neoplasm (essential thrombocythemia, polycythemia vera, symptomatic lower-risk myelofibrosis), systemic mastocytosis, adult T-cell leukemia/lymphoma, mycosis fungoides/sezary syndrome, primary cutaneous CD30+ T-cell lymphoproliferative disorders, hairy cell leukemia, Erdheim-Chester disease. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PEMAZYRE

**Products Affected**

- Pemazyre

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Cholangiocarcinoma-approve if the patient has unresectable locally advanced, gross residual, or metastatic disease and the tumor has a fibroblast growth factor receptor 2 (FGFR2) gene fusion or other rearrangement, as detected by an approved test AND the patient has been previously treated with at least one systemic therapy regimen. Myeloid/lymphoid neoplasms-approve if the patient has eosinophilia and the cancer has fibroblast growth factor receptor 1 (FGFR1) rearrangement, as detected by an approved test. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PHENYLBUTYRATE

**Products Affected**

- sodium phenylbutyrate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PHEOCHROMOCYTOMA

**Products Affected**

- metyrosine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior medication trials |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial and continuation therapy for metyrosine) |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | If the requested drug is metyrosine for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin). If the requested drug is metyrosine for continuation therapy, approve if the patient is currently receiving metyrosine or has received metyrosine in the past. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PHOSPHODIESTERASE-5 INHIBITORS

**Products Affected**

- sildenafil (pulm.hypertension) oral tablet
- tadalafil (pulm. hypertension)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use With Guanylate Cyclase Stimulators. |
| **Required Medical Information** | Diagnosis, right heart cath results |
| **Age Restrictions** | |
| **Prescriber Restrictions** | For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Pulmonary arterial hypertension (PAH), are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Raynaud's Phenomenon-approve if the patient has tried one calcium channel blocker or if use of a calcium channel blocker is contraindicated. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets require confirmation that the indication is PAH or Raynaud's prior to reviewing for quantity exception. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Raynaud's Phenomenon |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PIQRAY

**Products Affected**

- Piqray

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer. Approve if the patient meets the following criteria (A, B, C, D, E and F): A) The patient is a postmenopausal female, male or pre/perimenopausal and is receiving ovarian suppression with a gonadotropin-releasing hormone (GnRH) agonist or has had surgical bilateral oophorectomy or ovarian irradiation AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, tamoxifen, toremifene or fulvestrant) AND F) Piqray will be used in combination with fulvestrant injection. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PIRFENIDONE

**Products Affected**

- pirfenidone oral tablet 267 mg, 801 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | IPF (initial therapy)- must have FVC greater than or equal to 40 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. IPF (continuation of therapy)- approve. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# POMALYST

**Products Affected**

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Kaposi Sarcoma/MM/Systemic light chain amyloidosis-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Primary CNS Lymphoma-approve if the patient has relapsed or refractory disease or is not a candidate for high-dose MTX or had intolerance to high-dose MTX. Kaposi Sarcoma-Approve if the patient meets one of the following (i or ii): i. patient is Human Immunodeficiency Virus (HIV)-negative OR ii. patient meets both of the following (a and b): a) The patient is Human Immunodeficiency Virus (HIV)-positive AND b) The patient continues to receive highly active antiretroviral therapy (HAART). MM-approve if the patient has tried at least one other regimen. Systemic light chain amyloidosis- approve if this is used in combination with dexamethasone and pt tried at least one other regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Systemic Light Chain Amyloidosis, Primary Central Nervous System (CNS) Lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# POSACONAZOLE (ORAL)

**Products Affected**

- posaconazole oral tablet,delayed release (DR/EC)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Aspergillus/Candida prophy, mucormycosis-6 mo, all others-3 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Mucomycosis - maintenance, fusariosis, invasive - treatment fungal infections (systemic) in patients with human immunodeficiency virus (HIV) infections (e.g., histoplasmosis, coccidioidomycosis) - treatment. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PRALUENT

**Products Affected**

- Praluent Pen

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use of Leqvio or Repatha. |
| **Required Medical Information** | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history (as specified in the Other Criteria field) |
| **Age Restrictions** | HeFH - 8 years and older. All other - 18 years of age and older. |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | HYPERLIPIDEMIA WITH HeFH (both A and B): A) meets (a, b, c, or d): a) untreated LDL-C greater than or equal to 190 mg/dL (or 155 mg/dL if less than 16 years old), b) phenotypic confirmation (Note 1) of HeFH, c) Dutch Lipid Network criteria score greater than 5, or d) Simon Broome criteria met threshold for definite or possible/probable, B) meets (a or b): a) tried one high-intensity statin (throughout, see Definition 1 below) and LDL-C remains 70 mg/dL or higher or b) statin intolerant (throughout, see Definition 2 below). ESTABLISHED CVD (both A and B): A) patient has/had one of the following conditions: prior MI, ACS, angina, CVA or TIA, CAD, PAD, coronary or other arterial revascularization procedure, B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 55 mg/dL or higher or b) statin intolerant. PRIMARY HYPERLIPIDEMIA (not associated with established CVD, HeFH, or HoFH) [A or B]: A) tried one high-intensity statin and ezetimibe for 8 weeks or longer and LDL-C remains 70 mg/dL or higher or B) statin intolerant. HYPERLIPIDEMIA WITH HoFH (both A and B): A) meets (a or b): a) phenotypic confirmation of HoFH, or b) meets (i and ii): i) untreated LDL-C greater than 400 mg/dL or treated LDL-C greater than or equal to 300 mg/dL, and ii) clinical manifestations of HoFH before 10 years of age or at least one parent with untreated LDL-C or total cholesterol consistent with FH, AND B) meets (a or b): a) tried one high-intensity statin and LDL-C remains 70 mg/dL or higher or b) statin intolerant. Note 1: Examples include mutations at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK) or low-density lipoprotein receptor adaptor protein (LDLRAP1) gene. Definition 1: High intensity statin defined as atorvastatin greater than or equal to 40 mg daily or rosuvastatin greater than or equal to 20 mg daily. Definition 2: Statin intolerance defined as experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved upon discontinuation of the statin. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PREVYMIS

**Products Affected**

- Prevymis oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For prophylaxis of cytomegalovirus (CMV) infection or disease in allogeneic hematopoietic stem cell transplant (HSCT) recipients: 1) the patient is CMV-seropositive, AND 2) the requested drug will not be used beyond day 100 post-transplantation. For prophylaxis of CMV disease in kidney transplant recipients: 1) the donor is CMV seropositive (D+), 2) the patient/recipient is CMV seronegative (R-), AND 3) the requested drug will not be used beyond day 200 post-transplantation. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# PROMACTA

**Products Affected**

- Promacta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Immune Thrombocytopenia or Aplastic Anemia, prescribed by, or after consultation with, a hematologist (initial therapy). Hep C, prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy). Post-transplant, prescribed by or in consult with a hematologist, oncologist or stem cell transplant specialist physician (initial) |
| **Coverage Duration** | ImmuneThrombo/MDS init3mo,cont1yr,AAinit4mo,cont1yr,Thrombo/HepC1yr,Transplant-init3mo,cont6mo |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Thrombocytopenia in patients with immune thrombocytopenia, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy (e.g., systemic corticosteroids, intravenous immunoglobulin, anti-D immunoglobulin, Nplate, Tavalisse, Doptelet, rituximab) or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial - approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliter) AND tried one immunosuppressant therapy (e.g., cyclosporine) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Thrombocytopenia post-allogeneic transplantation, initial - approve if, according to the prescriber, the patient has poor graft function AND has a platelet count less than 50,000/mcL. Cont- patient demonstrated a beneficial clinical response. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Thrombocytopenia in Myelodysplastic Syndrome (MDS), Thrombocytopenia in a patient post-allogeneic transplantation |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# PYRIMETHAMINE

**Products Affected**

- pyrimethamine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Patient's immune status (Toxoplasma gondii Encephalitis, chronic maintenance and prophylaxis, primary) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# QINLOCK

**Products Affected**

- Qinlock

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other therapies tried |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Gastrointestinal stromal tumor (GIST)-approve if the patient has tried imatinib or avapritinib tablets, AND the patient meets one of the following criteria (i, ii, or iii): i. Patient has tried sunitinib and regorafenib tablets, OR ii. Patient has tried dasatinib tablets, OR iii. Patient is intolerant of sunitinib. Melanoma, cutaneous-approve if the patient has metastatic or unresectable disease, AND the patient has an activating KIT mutation, AND the patient has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Melanoma, cutaneous |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# QUININE SULFATE

**Products Affected**

- quinine sulfate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For babesiosis: the requested drug is prescribed in combination with clindamycin |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 month |
| **Other Criteria** | Chloroquine-sensitive Plasmodium falciparum malaria: Failure, contraindication or intolerance to chloroquine or hydroxychloroquine. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Babesiosis, uncomplicated Plasmodium vivax malaria. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# RADICAVA ORS

**Products Affected**

- Radicava ORS Starter Kit Susp

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | ALSFRS-R score |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist, a neuromuscular disease specialist, or a physician specializing in the treatment of ALS (initial and continuation). |
| **Coverage Duration** | Initial, 6 months. Continuation, 6 months |
| **Other Criteria** | ALS, initial therapy - approve if the patient meets ALL of the following criteria: 1. According to the prescribing physician, the patient has a definite or probable diagnosis of ALS, based on the application of the El Escorial or the revised Airlie house diagnostic criteria AND 2. Patient has a score of two points or more on each item of the ALS Functional Rating Scale - Revised (ALSFRS-R) [ie, has retained most or all activities of daily living], AND 3. Patient has adequate respiratory function according to the prescriber, AND 4. Patient has received or is currently receiving riluzole tablets. Note-a trial of Tiglutik or Exservan would also count. ALS, continuation therapy - approve if, according to the prescribing physician, the patient continues to benefit from therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# RETEVMO

**Products Affected**

- Retevmo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Medullary Thyroid Cancer/Thyroid Cancer/Solid tumors-2 years and older, all others 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has recurrent, advanced or metastatic disease AND the tumor is RET fusion-positive. Thyroid cancer-approve if the patient has rearranged during transfection (RET) fusion positive or RET mutation positive disease or RET pathogenic variant AND the patient meets i or ii: i. patient has anaplastic thyroid cancer OR ii. the disease requires treatment with systemic therapy and patient has medullary thyroid cancer or the disease is radioactive iodine-refractory. Solid tumors-approve if the patient has recurrent, advanced or metastatic disease and the tumor is rearranged during transfection (RET) fusion-positive. Histiocytic neoplasm-approve if the patient has a rearranged during transfection (RET) fusion and has Langerhans cell histiocytosis or Erdheim Chester disease or Rosai-Dorfman disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Anaplastic thyroid carcinoma, histiocytic neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# REVCOVI

**Products Affected**

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, lab values, genetic tests (as specified in the Other Criteria field) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with, an immunologist, hematologist/oncologist, or physician that specializes in ADA-SCID or related disorders. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | ADA-SCID - approve if the patient had absent or very low (less than 1% of normal) ADA catalytic activity at baseline (i.e., prior to initiating enzyme replacement therapy) OR if the patient had molecular genetic testing confirming bi-allelic pathogenic variants in the ADA gene. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# REVUFORJ

**Products Affected**

- Revuforj

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 1 year and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | ACUTE LEUKEMIA-patient has relapsed or refractory disease and the disease is positive for a lysine methyltransferase 2A (KMT2A) gene translocation. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# REZDIFFRA

**Products Affected**

- Rezdiffra

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older (initial) |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist, gastroenterologist, or hepatologist (initial/continuation) |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | INITIAL THERAPY: METABOLIC-DYSFUNCTION ASSOCIATED STEATOHEPATITIS (MASH)/NON-ALCOHOLIC STEATOHEPATITIS (NASH) WITH MODERATE-ADVANCED LIVER FIBROSIS: All of (i, ii, iii, and iv): i) Diagnosed by (a or b): a) Liver biopsy performed within 3 years preceding treatment with Rezdiffra showing non-alcoholic fatty liver disease activity score of greater than or equal to 4 with a score of greater than or equal to 1 in ALL of the following: steatosis, ballooning and lobular inflammation, or b) One of the following within 6 months preceding treatment with Rezdiffra (1, 2 or 3): 1) Elastography (e.g. vibration-controlled transient elastography (e.g., FibroScan), transient elastography, magnetic resonance elastography, acoustic radiation force impulse imaging, shear wave elastography) or 2) Computed tomography or 3) Magnetic resonance imaging, and ii) stage F2 or F3 fibrosis prior to Rezdiffra and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise) and iv) Prescriber attestation that member is currently receiving standard of care management for concomitant related conditions, including type 2 diabetes, dyslipidemia, and hypertension. CONTINUATION THERAPY (on therapy less than 1 year or restarting, review as initial therapy): MASH/NASH: All of (i, ii, iii, and iv): i) completed greater than or equal to 1 year of therapy and has not had worsening of fibrosis or MASH/NASH, and ii) has not progressed to stage F4 (cirrhosis) and iii) This will be used in combination with appropriate diet and exercise therapy (prescriber confirms the patient has received counseling on diet and exercise) and iv) Prescriber attestation that member is currently receiving standard of care management for concomitant related conditions, including type 2 diabetes, dyslipidemia, and hypertension. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# REZLIDHIA

**Products Affected**

- Rezlidhia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acute myeloid leukemia-approve if the patient has relapsed or refractory disease and the patient has isocitrate dehydrogenase-1 (IDH1) mutation positive disease as detected by an approved test. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# RINVOQ

**Products Affected**

- Rinvoq

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a biologic or with a targeted synthetic oral small molecule drug, Concurrent use with other potent immunosuppressants, or concurrent use with a biologic immunomodulator. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | PsA/JIA - 2 years and older (initial therapy), RA/UC/AS/CD/nr-axSpA/GCA-18 years and older (initial therapy), AD-12 years and older (initial therapy) |
| **Prescriber Restrictions** | RA/AS/Non-Radiographic Spondy/JIA/GCA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. AD-prescr/consult with allergist, immunologist or derm. UC/CD-prescribed by or in consultation with a gastroenterologist. (all apply to initial therapy only) |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA)/PSORIATIC ARTHRITIS (PsA)/ULCERATIVE COLITIS (UC)/ANKYLOSING SPONDYLITIS (AS)/CROHN'S DISEASE (CD)/ JUVENILE IDIOPATHIC ARTHRITIS (JIA): 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. ATOPIC DERMATITIS (AD): 4-month trial of at least one systemic therapy (e.g., Dupixent [dupilumab subcutaneous injection], Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemluvio (nemolizumab-ilto subcutaneous injection), and Adbry [tralokinumab-ldrm subcutaneous injection]. Azathioprine, cyclosporine, or mycophenolate mofetil also count.) or unable to tolerate a 4-month trial. NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS (A and B): A) objective signs of inflammation defined as having at least one of the following (a or b): a) C-reactive protein elevated beyond the upper limit of normal or b) sacroiliitis reported on MRI and B) 3-month trial of at least one TNFi or was unable to tolerate a 3-month trial. GIANT CELL ARTERITIS: tried one systemic corticosteroid. CONTINUATION THERAPY: ALL INDICATIONS: patient responded to therapy. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# RINVOQ LQ

**Products Affected**

- Rinvoq LQ

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a biologic or with a targeted synthetic DMARD, other potent immunosuppressants, other janus kinase inhibitors, or a biologic immunomodulator. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | PsA-2 years and older (initial therapy) |
| **Prescriber Restrictions** | JIA-prescribed by or in consultation with a rheumatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or a dermatologist (initial therapy) |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: JUVENILE IDIOPATHIC ARTHRITIS (JIA)/ PSORIATIC ARTHRITIS (PsA) - 3-month trial of at least one tumor necrosis factor inhibitor (TNFi) or unable to tolerate a 3-month trial. CONTINUATION THERAPY: ALL INDICATIONS - patient responded to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ROMVIMZA

**Products Affected**

- Romvimza

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | TENOSYNOVIAL GIANT CELL TUMOR (PIGMENTED VILLONODULAR SYNOVITIS)-tumor is not amenable to improvement with surgery. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ROZLYTREK

**Products Affected**

- Rozlytrek

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | NSCLC-18 years and older, Solid Tumors-1 month and older, Pediatric Diffuse High-Grade Glioma-less than 18 years old |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Solid Tumors-Approve if the patient's tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic OR surgical resection of tumor will likely result in severe morbidity. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease and the mutation was detected by an approved test. Pediatric Diffuse High-Grade Glioma- approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the medication is used either as adjuvant therapy or for recurrent or progressive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Pediatric Diffuse High-Grade Glioma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# RUBRACA

**Products Affected**

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer- Approve if (A, B and C): A) the patient is in complete or partial response after a platinum-based chemotherapy regimen, and B) meets (i or ii): i) the patient is in complete or partial response to first-line primary treatment or ii) patient has recurrent disease and has a BRCA mutation, and C) for new starts, the patient has tried the preferred product Lynparza, unless the prescriber indicates that Lynparza is inappropriate for the patient's specific clinical situation. Castration-Resistant Prostate Cancer - Approve if the patient meets the following criteria (A, B, C, and D): A) The patient has metastatic disease that is BRCA-mutation positive (germline and/or somatic) AND B) The patient meets one of the following criteria (i or ii): i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR ii. The patient has had a bilateral orchiectomy AND C) The patient has been previously treated with at least one androgen receptor-directed therapy, and D) for new starts, the patient has tried one of the preferred products, Lynparza or Talzenna, unless the prescriber indicates that both Lynparza and Talzenna are inappropriate for the patient's specific clinical situation. Pancreatic adenocarcinoma-approve if pt has a BRCA mutation or PALB2 mutation AND pt has tried platinum-based chemotherapy AND has not had disease progression following the most recent platinum-based chemotherapy. Uterine leiomyosarcoma-approve if the patient has BRCA2-altered disease and has tried one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Uterine Leiomyosarcoma, Pancreatic Adenocarcinoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# RUFINAMIDE

**Products Affected**

- rufinamide

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Patients 1 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Initial therapy-approve if rufinamide is being used for adjunctive treatment. Continuation-approve if the patient is responding to therapy |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Treatment-Refractory Seizures/Epilepsy |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# RYDAPT

**Products Affected**

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For AML, FLT3 status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML-approve if the patient is FLT3-mutation positive as detected by an approved test. Myeloid or lymphoid Neopasms with eosinophilia-approve if the patient has an FGFR1 rearrangement or has an FLT3 rearrangement. Indolent systemic mastoytosis-pt has symptomatic disease and has tried at least one systemic regimen. Smoldering systemic mastocytosis-pt has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloid or lymphoid Neopasms with eosinophilia, indolent systemic mastocytosis, smoldering systemic mastocytosis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# SAPROPTERIN

**Products Affected**

- sapropterin oral powder in packet 100 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Palynziq |
| **Required Medical Information** | Diagnosis, Phe concentration |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy) |
| **Coverage Duration** | Initial-12 weeks, Continuation-1 year |
| **Other Criteria** | Initial - approve. Continuation (Note-if the patient has received less than 12 weeks of therapy or is restarting therapy with sapropterin should be reviewed under initial therapy) - approve if the patient has had a response to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# SCEMBLIX

**Products Affected**

- Scemblix

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Chronic Myeloid Leukemia (CML)-approve if the patient meets the following (A and B): A) Patient has Philadelphia chromosome-positive or BCR::ABL1-positive chronic myeloid leukemia, AND B) Patient meets one of the following (i, ii or iii): i. Patient has newly diagnosed disease, OR ii. The chronic myeloid leukemia is T315I-positive, OR iii. Patient has tried at least one other tyrosine kinase inhibitor. Note: Examples of tyrosine kinase inhibitors include imatinib, Bosulif (bosutinib tablets), Iclusig (ponatinib tablets), dasatinib, and nilotinib capsules. Myeloid/Lymphoid Neoplasms with Eosinophilia - approve if the tumor has an ABL1 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloid/Lymphoid Neoplasms with Eosinophilia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# SIGNIFOR

**Products Affected**

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# SIRTURO

**Products Affected**

- Sirturo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# SKYRIZI

**Products Affected**

- Skyrizi subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# SOFOSBUVIR/VELPATASVIR

**Products Affected**

- sofosbuvir-velpatasvir

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination use with other direct acting antivirals, excluding ribavirin. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 3 years or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| **Coverage Duration** | Criteria will be applied consistent with current AASLD/IDSA guidance. |
| **Other Criteria** | Criteria will be applied according to AASLD guidelines. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Indications consistent with current AASLD/IDSA guidance |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# SOMAVERT

**Products Affected**

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, previous therapy, concomitant therapy |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | ACROMEGALY (A or B): A) inadequate response to surgery and/or radiotherapy or patient not an appropriate candidate or B) patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) and has pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# SORAFENIB

**Products Affected**

- sorafenib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Bone cancer, approve if the patient has recurrent chordoma or has osteosarcoma and has tried one standard chemotherapy regimen. GIST, approve if the patient has tried TWO of the following: imatinib mesylate, avapritinib, sunitinib, dasatinib, ripretinib or regorafenib. Differentiated (ie, papillary, follicular, oncocytic) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried at least one systemic therapy. AML - Approve if disease is FLT3-ITD mutation positive as detected by an approved test and the medication is used in combination with azacitidine or decitabine or patient has had an allogeneic stem cell transplant and is in remission. Renal cell carcinoma (RCC)-approve if the patient has relapsed or advanced clear cell histology and the patient has tried at least one systemic therapy (e.g., Inlyta, Votrient, Sutent Cabometyx). Ovarian, fallopian tube, primary peritoneal cancer-approve if the patient has platinum resistant disease and sorafenib is used in combination with topotecan. HCC-approve if the patient has unresectable or metastatic disease. Soft tissue sarcoma-approve if the patient has angiosarcoma or desmoid tumors (aggressive fibromatosis) or solitary fibrous tumor/hemangiopericytoma. Myeloid/lymphoid neoplasms with eosinophilia-approve if the tumor has an FLT3 rearrangement. Please note for all diagnoses: Part B before Part D Step Therapy applies only to beneficiaries enrolled in an MA-PD plan |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Bone cancer, Soft tissue sarcoma, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, ovarian, fallopian tube, primary peritoneal cancer, myeloid/lymphoid neoplasms with eosinophilia |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# SPRYCEL

**Products Affected**

- dasatinib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis for which dasatinib is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For melanoma, cutaneous- KIT mutation and previous therapies. |
| **Age Restrictions** | GIST/bone cancer/ melanoma, cutaneous-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | For CML, patient must have Ph-positive or BCR::ABL1-positive CML. For ALL, patient must have Ph-positive ALL or ABL-class translocation. For Bone Cancer- approve if patient has chondrosarcoma or chordoma. GIST - approve if the patient has tried imatinib or avapritinib. For melanoma, cutaneous - approve if patient has metastatic or unresectable disease AND has an activating KIT mutation AND has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | GIST, bone cancer, melanoma cutaneous |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# STIVARGA

**Products Affected**

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# SUNITINIB

**Products Affected**

- sunitinib malate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TABRECTA

**Products Affected**

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Non-Small Cell Lung Cancer (NSCLC)-Approve if the patient has advanced or metastatic disease AND the tumor is positive for a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping or high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Non-small cell lung cancer with high-level MET amplification. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TADALAFIL

**Products Affected**

- tadalafil oral tablet 2.5 mg, 5 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Treatment of erectile dysfunction (ED) |
| **Required Medical Information** | Indication for which tadalafil is being prescribed. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 mos. |
| **Other Criteria** | Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TAFAMIDIS

**Products Affected**

- Vyndaqel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with other medications indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., Amvuttra (vutrisiran subcutaneous injection), Attruby (acoramidis tablets), Onpattro (patisiran lipid complex intravenous infusion), Tegsedi (inotersen subcutaneous injection), or Wainua [eplontersen subcutaneous injection]). Concurrent use of Vyndaqel and Vyndamax. |
| **Required Medical Information** | Diagnosis, genetic tests and lab results (as specified in the Other Criteria field) |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis-approve if patient meets (A, B and C): A) the diagnosis was confirmed by one of the following (i, ii or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy), ii. tissue biopsy with confirmatory TTR amyloid typing by mass spectrometry, immunoelectron microscopy or immunohistochemistry OR iii. patient had genetic testing which, according to the prescriber, identified a TTR pathogenic variant AND B) Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum), and C) patient has heart failure but does not have NYHA class IV disease. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | No |

# TAFINLAR

**Products Affected**

- Tafinlar

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Low grade glioma, solid tumors- 1 year and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Low grade glioma- approve if pt has BRAF V600 mutation-positive disease and this medication will be taken with Mekinist (trametinib). Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. NSCLC-approve if pt has recurrent, advanced, or metastatic disease AND BRAF V600 mutation-positive disease. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or oncocytic) AND recurrent or metastatic disease AND the patient has BRAF-positive disease. Histiocytic neoplasm-approve if (A and B): A) patient has Langerhans cell histiocytosis or Erdheim Chester disease AND B) patient has BRAF V600-mutation positive disease. Solid tumors [examples: biliary tract cancer, brain metastases due to melanoma, high-grade gliomas, ovarian/fallopian tube/primary peritoneal cancer, differentiated thyroid carcinoma, gastrointestinal stromal tumors, gastric cancer, esophageal and esophagogastric junction cancers, salivary gland tumors, occult primary, pancreatic adenocarcinoma, neuroendocrine tumors, ampullary adenocarcinoma]-approve if BRAF V600 mutation-positive disease AND medication will be taken in combination with Mekinist (trametinib). Hairy Cell Leukemia, approve if pt has not previously been treated with a BRAF inhibitor therapy and this will be used for relapsed/refractory disease and will be taken in combination with Mekinist. Small bowel adenocarcinoma, approve if pt has BRAF V600E mutation-positive advanced or metastatic disease and this will be used with Mekinist AND (i or ii): i) this will be used as initial therapy and pt has received previous FOLFOX/CAPEOX therapy in the adjuvant setting within the past 12 months or has a contraindication, or (ii) this will be used as second-line and subsequent therapy. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Histiocytic neoplasm, hairy cell leukemia |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TAGRISSO

**Products Affected**

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-EGFR Mutation Positive (other than EGFR T790M-Positive Mutation)-approve if the patient has advanced or metastatic disease, has EGFR mutation-positive NSCLC as detected by an approved test. Note-examples of EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. NSCLC-EGFR T790M mutation positive-approve if the patient has advanced or metastatic EGFR T790M mutation-positive NSCLC as detected by an approved test and has progressed on treatment with at least one of the EGFR tyrosine kinase inhibitors. NSCLC-Post resection-approve if the patient has completely resected disease and has received previous adjuvant chemotherapy or if the patient is inegligible to receive platinum based chemotherapy and the patient has EGFR exon 19 deletions or exon 21 L858R substitution mutations, as detected by an approved test. NSCLC- Unresectable Stage III - approve if the patient has locally advanced, unresectable (stage III) disease AND EGFR exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an approved test AND not had disease progression during or following platinum-based chemoradiation therapy. (Note:  Patients could have received concurrent or sequential chemoradiation therapy.) |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TALZENNA

**Products Affected**

- Talzenna

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Recurrent or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive disease. Prostate cancer - approve if the patient has metastatic castration resistant prostate cancer, AND is using this medication concurrently with a gonadotropin-releasing hormone (GnRH) analog or has had a bilateral orchiectomy AND the patient has homologous recombination repair (HRR) gene-mutated disease [Note: HRR gene mutations include ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C] AND the medication is used in combination with Xtandi (enzalutamide capsules and tablets). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TAZAROTENE

**Products Affected**

- tazarotene topical cream 0.1 %
- tazarotene topical gel

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Cosmetic uses |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TAZVERIK

**Products Affected**

- Tazverik

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Epithelioid Sarcoma-16 years and older, Follicular Lymphoma-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Epitheliod Sarcoma-approve if the patient has metastatic or locally advanced disease and the patient is not eligible for complete resection. Follicular Lymphoma-approve if the patient has relapsed or refractory disease and there are no appropriate alternative therapies or the patient has tried at least two prior systemic therapies. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TEPMETKO

**Products Affected**

- Tepmetko

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease and the tumor is positive for mesenchymal-epithelial transition (MET) exon 14 skipping mutations or patient has high-level MET amplification, as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Non-small cell lung cancer with high-level MET amplification. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TERIPARATIDE

**Products Affected**

- Bonsity
- teriparatide subcutaneous pen injector 20 mcg/dose (560mcg/2.24mL)

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with other medications for osteoporosis |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | High risk for fracture-2 yrs, Not high risk-approve a max of 2 yrs of therapy (total)/lifetime. |
| **Other Criteria** | INITIAL THERAPY: Postmenopausal Osteoporosis (PMO) Treatment, Increase Bone Mass in Men (see Note 1 below) with Primary or Hypogonadal Osteoporosis, and Treatment of Glucocorticosteroid-Induced Osteoporosis (GIO): (one of A, B, C, D or E): A) tried one oral bisphosphonate or cannot take due to swallowing difficulties or inability to remain upright after administration, B) pre-existing gastrointestinal condition (e.g., esophageal lesions/ulcers, abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), C) tried an IV bisphosphonate (PMO-ibandronate or zoledronic acid, all other diagnoses-zoledronic acid), D) severe renal impairment (creatinine clearance [CrCL] less than 35 mL/min) or chronic kidney disease (CKD), or E) patient had an osteoporotic fracture or fragility fracture at any time in the past. CONTINUATION THERAPY: ALL INDICATIONS: if the patient has taken teriparatide for two years, approve if the patient is at high risk for fracture. Examples of high risk for fracture include a previous osteoporotic fracture or fragility fracture, receipt of medications that increase the risk of osteoporosis, advanced age, and very low bone mineral density. Note 1: a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TETRABENAZINE

**Products Affected**

- tetrabenazine

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Chorea associated with Huntington's Disease-approve if the diagnosis of Huntington's Disease is confirmed by genetic testing. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# THALOMID

**Products Affected**

- Thalomid oral capsule 100 mg, 50 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | MM, histiocytic neoplasms-18 years and older, medulloblastoma- less than 18 years old |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Erythem Nodosum Leprosum-approve. Multiple Myeloma-approve. Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried at least two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Prurigo nodularis, approve. Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried at least two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). Kaposi Sarcoma-approve if the patient has tried at least one medication AND has relapsed or refractory disease. Castleman disease-approve if the patient has multicentric disease and is negative for the human immunodeficiency virus (HIV) and human herpesvirus-8 (HHV-8). Histiocytic neoplasms-approve if (A or B): A) pt has Langerhans cell histiocytosis with either (i or ii): i) single-system multifocal skin disease or ii) relapsed or refractory disease, or B) pt has or Rosai-Dorfman cutaneous disease. Medulloblastoma- approve if pt has recurrent or progressive disease AND medication is being used as a part of the MEMMAT regimen (i.e. Thalomid, celecoxib, fenofibrate, oral etoposide, cyclophosphamide, bevacizumab, and intraventricular etoposide). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Discoid lupus erythematosus or cutaneous lupus erythematosus, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Kaposi Sarcoma, Castleman Disease, histiocytic neoplasms, medulloblastoma. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TIBSOVO

**Products Affected**

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, IDH1 Status |
| **Age Restrictions** | All diagnoses (except chondrosarcoma)-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML- approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive, as detected by an approved test. Cholangiocarcinoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive and has been previously treated with at least one chemotherapy regimen (Part B before Part D Step Therapy - applies only to beneficiaries enrolled in an MA-PD plan). Chondrosarcoma-approve if the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. Central nervous system cancer-approve if the patient has oligodendroglioma or astrocytoma. Myelodysplastic Syndrome-approve if patient has isocitrate dehydrogenase-1 (IDH1) mutation-positive disease AND relapsed or refractory disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Chondrosarcoma, Central nervous system cancer |
| **Part B Prerequisite** | Yes |
| **Prerequisite Therapy Required** | Yes |

# TOBRAMYCIN (NEBULIZATION)

**Products Affected**

- tobramycin in 0.225 % NaCl

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Bronchiectasis, Non-cystic fibrosis-18 years and older |
| **Prescriber Restrictions** | CF-prescr/consult w/pulm/phys specializes in tx of CF.Bronchiectasis, non CF-prescr/consult w/pulm |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Part B versus Part D determination will be made at time of prior authorization review per CMS guidance. Cystic fibrosis/Bronchiectasis, non-cystic fibrosis-approve if the patient has pseudomonas aeruginosa in the culture of the airway. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Bronchiectasis, non-cystic fibrosis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TOLVAPTAN

**Products Affected**

- tolvaptan

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with Jynarque. |
| **Required Medical Information** | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion). |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 30 days for initial therapy, 3 months for continuation of therapy |
| **Other Criteria** | Hyponatremia, initial therapy (including new starts, patients on therapy for less than 30 days, and patients restarting therapy) - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on tolvaptan and has received less than 30 days of therapy. Hyponatremia, continuation of therapy for patients established on therapy for at least 30 days - approve if the serum sodium level has increased from baseline (prior to initiating the requested drug) OR if the patient experienced improvement in at least one symptom, such as nausea, vomiting, headache, lethargy, or confusion. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

**Products Affected**

- Eucrisa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months. |
| **Other Criteria** | Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid. |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TOPICAL RETINOID PRODUCTS

**Products Affected**

- tretinoin
- tretinoin microspheres topical gel 0.04 %, 0.1 %

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for cosmetic use. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 12 months |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TOPIRAMATE/ZONISAMIDE

**Products Affected**

- Eprontia
- Zonisade

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Coverage is not provided for weight loss or smoking cessation. |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | |
| **Indications** | All Medically-accepted Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TRANSDERMAL FENTANYL

**Products Affected**

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TREMFYA SC

**Products Affected**

- Tremfya Pen Induction Pk-Crohn
- Tremfya Pen subcutaneous pen injector 200 mg/2 mL
- Tremfya subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | PP/UC/CD/PsA-18 years of age and older (initial therapy) |
| **Prescriber Restrictions** | PP-Prescribed by or in consultation with a dermatologist (initial therapy only). PsA-prescribed by or in consultation with a dermatologist or rheumatologist (initial therapy). UC/CD-prescribed by or in consultation with a gastroenterologist (initial therapy). |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | PP, intial therapy - approve if the pt meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: a biologic that is not a biosimilar of the requested product will also count) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. ULCERATIVE COLITIS- pt will receive 3 induction doses with Tremfya IV within 3 months of initiating Tremfya SC AND (A or B): A) tried a systemic therapy (e.g., 6-MP, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a CS) or B) has pouchitis and tried therapy with an antibiotic, probiotic, CS enema, or mesalamine (Rowasa) enema. CROHN'S DISEASE (CD) [one of A, B, C, or D]: A) tried or currently taking corticosteroid (CS) or CS is contraindicated, B) tried one other conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX], certolizumab, infliximab, ustekinumab, vedolizumab), C) had ileocolonic resection, or D) enterocutaneous (perianal or abdominal) or rectovaginal fistulas. PP/PsA/UC/CD continuation of therapy - approve it the pt is responding to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TRIENTINE

**Products Affected**

- trientine oral capsule 250 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician. |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | For Wilson's Disease, approve if the patient meets A and B: A) Diagnosis of Wilson's disease is confirmed by ONE of the following (i or ii): i. Genetic testing results confirming biallelic pathogenic ATP7B mutations (in either symptomatic or asymptomatic individuals), OR ii. Confirmation of at least two of the following (a, b, c, or d): a. Presence of Kayser-Fleischer rings, OR b. Serum ceruloplasmin levels less than 20mg/dL, OR c. Liver biopsy findings consistent with Wilson's disease, OR d. 24-hour urinary copper greater than 40 micrograms/24 hours, AND B) Patient meets ONE of the following: 1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant, OR 6) the patient has been started on therapy with trientine. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# TRIKAFTA

**Products Affected**

- Trikafta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Combination therapy with other CF transmembrane conductance regulator modulators. |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 2 years of age and older |
| **Prescriber Restrictions** | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF |
| **Coverage Duration** | 1 year |
| **Other Criteria** | CF -Approve if the pt meets A, B and C: A) pt has at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is considered to be pathogenic or likely pathogenic variant, and B) pt must have positive CF newborn screening test or family history of CF or clinical presentation consistent with signs and symptoms of CF and C) evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by i, ii, or iii: (i) elevated sweat chloride test or (ii) two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations or (iii) abnormal nasal potential difference. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TRUQAP

**Products Affected**

- Truqap

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer-Approve if the patient meets the following (A, B, C, D and E): A) Patient has locally advanced or metastatic disease, AND B) Patient has hormone receptor positive (HR+) disease, AND C) Patient has human epidermal growth factor receptor 2 (HER2)-negative disease, AND D) Patient has at least one phosphatidylinositol 3-kinase (PIK3CA), serine/threonine protein kinase (AKT1), or phosphatase and tensin homolog (PTEN)-alteration, AND E) Patient meets one of the following (i or ii): i. Patient has had progression with at least one endocrine-based regimen in the metastatic setting (Note: Examples of endocrine therapy include anastrozole, exemestane, and letrozole.) and has had progression with at least one cyclin-dependent kinase (CDK) 4/6 inhibitor in the metastatic setting (Note: Examples of CDK4/6 inhibitor include: Ibrance (palbociclib tablets or capsules), Verzenio (abemaciclib tablets), Kisqali (ribociclib tablets), Kisqali Femara Co-Pack (ribociclib and letrozole tablets) OR ii. Patient has recurrence on or within 12 months of completing adjuvant endocrine therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# TUKYSA

**Products Affected**

- Tukysa

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Breast Cancer-approve if the patient has recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease, has received at least one prior anti-HER2-based regimen in the metastatic setting and Tukysa is used in combination with trastuzumab and capecitabine. Colon/Rectal Cancer-approve if the requested medication is used in combination with trastuzumab, patient has unresectable or metastatic disease, human epidermal growth factor receptor 2 (HER2)-amplified disease, AND Patient's tumor or metastases are wild-type RAS (KRAS wild-type and NRAS wild-type). Biliary tract cancer-approve if the patient meets all of (a, b, c, and d): a) unresectable or metastatic disease, b) HER2 positive disease, c) tried at least one systemic regimen, d) will use in combination with trastuzumab. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Biliary tract cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# TURALIO

**Products Affected**

- Turalio oral capsule 125 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)- approve if, according to the prescriber, the tumor is not amenable to improvement with surgery. Histiocytic Neoplasms-approve if the patient has a colony stimulating factor 1 receptor (CSF1R) mutation AND has one of the following conditions (i, ii, or iii): i. Langerhans cell histiocytosis OR ii. Erdheim-Chester disease OR iii. Rosai-Dorfman disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Histiocytic Neoplasms |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# TYENNE SC

**Products Affected**

- Tyenne Autoinjector
- Tyenne subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD. |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | Interstitial lung disease-18 years and older (initial and continuation). GCA/RA-18 years and older (initial only). SJIA/PJIA-2 years and older (initial only). |
| **Prescriber Restrictions** | RA/GCA/PJIA/SJIA - Prescribed by or in consultation with a rheumatologist (initial therapy only). Lung disease-presc/consult-pulmonologist or rheum (initial and cont) |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: RHEUMATOID ARTHRITIS (RA) [A or B): A) tried two of the following: preferred adalimumab product, Enbrel, Rinvoq or Xeljanz/XR (Note: trials with the following will also count: Cimzia, infliximab, Kevzara, golimumab SC/IV, non-preferred adalimumab product, Orencia), or B) heart failure or a previously treated lymphoproliferative disorder. POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS (PJIA) [A or B]: A) tried two of the following: preferred adalimumab product, Enbrel, Rinvoq, Xeljanz. (Note: trials with Kevzara, infliximab, Orencia or a non-preferred adalimumab product will also count), or B) heart failure or a previously treated lymphoproliferative disorder. SYSTEMIC-ONSET JIA (SJIA) [one of A, B, or C]: A) tried one other systemic agent (e.g., corticosteroid [CS], conventional synthetic DMARD [e.g., MTX, leflunomide, sulfasalazine], or B) tried Kineret (anakinra) or Ilaris (canakinumab for SC injection), or C) one-month trial of an NSAID. GIANT CELL ARTERITIS: tried one systemic CS. INTERSTITIAL LUNG DISEASE ASSOCIATED WITH SYSTEMIC SCLEROSIS (A and B): A) elevated acute phase reactants and B) diagnosis confirmed by high-resolution computed tomography. CONTINUATION THERAPY: ALL INDICATIONS: patient had a response to therapy. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# UCERIS

**Products Affected**

- budesonide oral tablet,delayed and ext.release

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# UPTRAVI

**Products Affected**

- Uptravi oral

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concurrent Use with Other Inhaled or Parenteral Prostacyclin Agents Used for Pulmonary Hypertension. |
| **Required Medical Information** | Confirmation of right heart catheterization, medication history (as described in Other Criteria) |
| **Age Restrictions** | |
| **Prescriber Restrictions** | PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist. |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Patient new to therapy must meet a) OR b): a) tried one or is currently taking one oral therapy for PAH for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# USTEKINUMAB SC

**Products Affected**

- Stelara subcutaneous
- Steqeyma
- ustekinumab subcutaneous

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD |
| **Required Medical Information** | Diagnosis, concurrent medications, previous drugs tried. |
| **Age Restrictions** | PP/PsA-6 years and older (initial therapy). UC/CD-18 years and older (initial therapy) |
| **Prescriber Restrictions** | Plaque psoriasis.Prescribed by or in consultation with a dermatologist (initial therapy). PsA-prescribed by or in consultation with a rheumatologist or dermatologist (initial therapy). CD/UC-prescribed by or in consultation with a gastroenterologist (initial therapy). |
| **Coverage Duration** | Approve through end of plan year |
| **Other Criteria** | INITIAL THERAPY: PLAQUE PSORIASIS (PP) [A or B]: A) tried one traditional systemic agent (e.g., methotrexate [MTX], cyclosporine, acitretin, psoralen plus PUVA) for at least 3 months, unless intolerant or B) contraindication to MTX. (Note: a 3-month trial or intolerance of at least one biologic that is not ustekinumab also counts.) CROHN'S DISEASE (CD) [A and B]: A) receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC, and B) (a, b, c or d): a) tried or is currently taking corticosteroids (CS), or CS are contraindicated, b) tried one conventional systemic therapy, c) has enterocutaneous (perianal or abdominal) or rectovaginal fistulas, or d) had ileocolonic resection to reduce the chance of CD recurrence. ULCERATIVE COLITIS (UC) [A and B]: A) receiving/received single IV loading dose within 2 months of initiating therapy with ustekinumab SC and B) meets one of the following (a or b): a) tried one systemic agent or b) has pouchitis and tried an antibiotic, probiotic, CS enema or mesalamine enema. CONTINUATION THERAPY: PP/PsA/CD/UC: patient has responded to therapy. ALL INDICATIONS, INITIAL AND CONTINUATION in addition to the above criteria: patients requesting Stelara must have a trial of ONE preferred ustekinumab biosimilar prior to approval. |
| **Indications** | All FDA-approved Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VALCHLOR

**Products Affected**

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Cutaneous lymphoma-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has smoldering subtype of adult T-cell leukemia/lymphoma. Langerhans cell histiocytosis-approve if the patient has unifocal Langerhans cell histiocytosis with isolated skin disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Adults with T-cell leukemia/lymphoma, Langerhans Cell Histiocytosis |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VALTOCO

**Products Affected**

- Valtoco

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, other medications used at the same time |
| **Age Restrictions** | |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiseizure medication(s). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VANFLYTA

**Products Affected**

- Vanflyta

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Acute Myeloid Leukemia: approve if the patient has FLT3-ITD mutation-positive disease as detected by an approved test. Myeloid or lymphoid neoplasms: approve if patient has eosinophilia and the tumor has FLT3 rearrangement. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Myeloid or lymphoid neoplasms |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VENCLEXTA

**Products Affected**

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapy |
| **Age Restrictions** | 18 years and older (all diagnoses except ALL) |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML-approve if used in combination with azacitidine, decitabine, or cytarabine. CLL/SLL- approve. ALL- approve if relapsed/refractory disease and will be used in combination with chemotherapy. Hairy cell leukemia- approve if disease resistance to BRAF inhibitor therapy. Mantle Cell Lymphoma- approve if (A or B): A) the patient has tried at least one systemic regimen or B) patient has TP53 mutation and will use this as induction therapy in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab intravenous infusion). MDS- approve if pt meets (A and B): A) pt meets (i or ii): (i) has chronic myelomonocytic leukemia-2 or (ii) has higher risk disease (note: includes international prognostic scoring system (IPSS-R) intermediate-, high-, or very-high risk disease) and B) will use in combination with azacitidine or decitabine. Myeloproliferative neoplasm- approve if pt has accelerated or blast phase disease and will use in combination with azacitidine or decitabine. Multiple Myeloma- approve if the patient has t (11,14) translocation AND has tried at least one systemic regimen for multiple myeloma AND Venclexta will be used in combination with dexamethasone. Systemic light chain amyloidosis-approve if the patient has t (11, 14) translocation and has tried at least one systemic regimen. Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma-approve if the patient has tried at least one systemic regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Mantle Cell Lymphoma, waldenstrom macroglobulinemia/lymphoplasmacytic lymphoma, multiple myeloma, systemic light chain amyloidosis, acute lymphoblastic leukemia, hairy cell leukemia, myelodysplastic syndrome, myeloproliferative neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VERSACLOZ

**Products Affected**

- Versacloz

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | For the treatment of a severely ill patient with schizophrenia who failed to respond adequately to standard antipsychotic treatment (i.e., treatment-resistant schizophrenia, new starts only): 1) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following generic products: aripiprazole, asenapine, lurasidone, olanzapine, quetiapine, risperidone, ziprasidone, AND 2) the patient has experienced an inadequate treatment response, intolerance, or has a contraindication to one of the following brand products: Caplyta, Rexulti, Secuado, Vraylar. |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Plan Year |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VERZENIO

**Products Affected**

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Breast cancer: HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Breast Cancer, Early-pt meets (A,B,C and D): A)Pt HR+disease, AND B) HER2-negative breast cancer, AND C)node-positive disease at high risk of recurrence AND D)meets 1 of the following (i or ii): i.Verzenio will be used in combo w/anastrozole, exemestane, or letrozole AND pt meets one of the following (a,b, or c): a)Pt is postmenopausal woman, OR b)Pt is pre/perimenopausal woman and meets one of the following 1 or 2:1-Pt receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation, OR c)Pt is man and pt is receiving a GnRH analog, OR ii.Verzenio will be used in combo with tamoxifen AND pt meets 1 of the following (a or b): a)Pt is postmenopausal woman or man OR b)Pt is pre/perimenopausal woman and meets 1 of the following 1 or 2:1-Pt is receiving ovarian suppression/ablation with a GnRH agonist, OR 2-Pt had surgical bilateral oophorectomy or ovarian irradiation. Breast Cancer-Recurrent or Metastatic in Women-pt meets (A, B and C): A)has HR+ disease, AND B)Pt meets 1 of following criteria (i or ii): i.Pt is postmenopausal woman, OR ii.Pt is pre/perimenopausal woman and meets 1 of the following (a or b): a)receiving ovarian suppression/ablation with a GnRH agonist, OR b)Pt had surgical bilateral oophorectomy or ovarian irradiation, AND C) either (1 or 2): 1) HER2-negative breast cancer and Pt meets 1 of following criteria (i, ii, or iii): i.Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.pt meets following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)has tried chemo for metastatic breast cancer or 2)has HER2-positive breast cancer and has received at least 3 prior anti-HER2-based regimens in metastatic setting and will use this in combo with fulvestrant and trastuzumab.Breast Cancer-Recurrent or Metastatic in Men-pt meets following criteria (A and B): A)HR+ disease, AND B)either (1 or 2): 1) HER2-negative disease and Pt meets 1 of following criteria (i, ii, or iii): i.Pt meets BOTH of the following conditions (a and b): a)receiving a GnRH analog, AND b)Verzenio will be used in combo with anastrozole, exemestane, or letrozole, OR ii.Verzenio will be used in combo with fulvestrant, OR iii.Pt meets the following conditions (a, b, and c): a)Verzenio will be used as monotherapy, AND b)Pt's breast cancer has progressed on at least 1 prior endocrine therapy, AND c)Pt has tried chemo for metastatic breast cancer, or 2) |
| | has HER2-positive disease and has received at least 3 prior anti-HER2-based regimen in metastatic setting and will use this medication in combo with fulvestrant and trastuzumab. Endometrial cancer-pt meets all of (A, B, And C): A)has recurrent or metastatic disease, and B)has estrogen receptor (ER)-positive tumors, and C)will be using in combination with letrozole. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |

| PA Criteria | Criteria Details |
|---|---|
| **Off Label Uses** | Endometrial cancer |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VIGABATRIN

**Products Affected**

- vigabatrin
- Vigadrone

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, medication history (complex partial seizures) |
| **Age Restrictions** | Refractory complex partial seizures - patients 2 years of age or older. Infantile spasms - patients less than or equal to 2 years of age |
| **Prescriber Restrictions** | Prescribed by, or in consultation with, a neurologist |
| **Coverage Duration** | Infantile spasms- 6 months. Treatment-Refractory Partial Seizures- initial 3 months, cont 1 year |
| **Other Criteria** | Infantile spasms-requested medication is being used as monotherapy. Treatment refractory complex partial seizures intial-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Treatment refractory complex partial seizures continuation- the patient is responding to therapy (e.g., reduced seizure severity, frequency, and/or duration). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VITRAKVI

**Products Affected**

- Vitrakvi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, NTRK gene fusion status |
| **Age Restrictions** | Pediatric Diffuse High-Grade Glioma- less than or equal to 21 years old |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Solid tumors - approve if the tumor is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity. Pediatric diffuse high grade glioma - approve if (A and B): A) tumor is positive for NTRK gene fusion and B) meets (i or ii): i) medication is used as adjuvant therapy or ii) medication is used for recurrent or progressive disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Pediatric Diffuse High-Grade Glioma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VIZIMPRO

**Products Affected**

- Vizimpro

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, EGFR status, exon deletions or substitutions |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | NSCLC-approve if the patient has advanced or metastatic disease, has sensitizing EGFR mutation-positive NSCLC as detected by an approved test. Note: Examples of sensitizing EGFR mutation-positive NSCLC include the following mutations: exon 19 deletions, exon 21 (L858R) substitution mutations, L861Q, G719X and S7681. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VONJO

**Products Affected**

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Myelofibrosis (MF), including primary MF, post-polycythemia Vera MF, and Post-Essential Thrombocythemia MF-approve if the patient meets either (A, B, or C): (A) meets (i and ii): i) the patient has a platelet count of less than 50 x 109 /L (less than 50,000/mcL) and (ii): meets (a or b): a) has higher-risk disease or b) has lower-risk disease and at least one disease-related symptom (examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis) OR (B) Patient has a platelet count of greater than or equal to 50 x 109 /L (greater than or equal to 50,000/mcL) and has higher-risk disease and has at least one disease-related symptom, OR (C) patient has myelofibrosis-associated anemia. Accelerated or blast phase myeloproliferative neoplasm- approve if the patient has at least one disease-related symptom (Examples: fatigue, fever, night sweats, weight loss, abdominal discomfort, splenomegaly, thrombocytosis, or leukocytosis). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Accelerated or blast phase myeloproliferative neoplasm |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VORANIGO

**Products Affected**

- Voranigo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 12 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | GLIOMAS-All of (A, B and C): A. Susceptible isocitrate dehydrogenase-1 (IDH1) or IDH2 mutation-positive disease, AND B. Grade 2 oligodendroglioma OR Grade 2 astrocytoma, AND C. Prior surgery, including biopsy, sub-total resection, or gross total resection |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VORICONAZOLE (ORAL)

**Products Affected**

- voriconazole

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Aspergillus-Prophy, systemic w/risk neutropenia-Prophy, systemic w/HIV-Prophy/Tx-6 mo, others-3 mo |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Aspergillus Infections - prophylaxis, oropharyngeal candidiasis (fluconazole-refractory) - treatment, candidia endophthalmitis - treatment, blastomycosis - treatment, fungal infections (systemic) in patients at risk of neutropenia - prophylaxis, fungal infections (systemic) in patients with human immunodeficiency virus (HIV) - prophylaxis or treatment. |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# VOTRIENT

**Products Affected**

- pazopanib

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Soft tissue sarcoma other than GIST-approve if the patient has advanced or metastatic disease and has ONE of the following: alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis, dermatofibrosarcoma protuberans with fibrosarcomatous transformation, non-adipocytic sarcoma or pleomorphic rhabdomyosarcoma. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent or metastatic disease. Renal Cell Carcinoma, Clear Cell or non-Clear Cell histology-approved if the patient has relapsed or advanced disease or VonHippel-Lindau disease. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease. GIST - approve if the patient has succinate dehydrogenase (SDH)-deficient GIST OR the patient has tried TWO of the following: Gleevec, Ayvakit, Sutent, Sprycel, Qinlock or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried at least one systemic therapy. Bone cancer-approve if the patient has chondrosarcoma and has metastatic widespread disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Differentiated (ie, papillary, follicular, oncocytic carcinoma) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST), Medullary thyroid carcinoma, bone cancer. |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# VOWST

**Products Affected**

- Vowst

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 30 days |
| **Other Criteria** | Prevention of recurrence of clostridioides difficile infection (CDI)-approve if the patient has completed a bowel prep, will not eat or drink for at least 8 hours prior to the first dose and will complete their antibacterial treatment for recurrent CDI 2-4 days before initiating treatment with Vowst and Vowst will not be used for the TREATMENT of CDI. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# WELIREG

**Products Affected**

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# WINREVAIR

**Products Affected**

- Winrevair

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | 18 years and older (initial) |
| **Prescriber Restrictions** | Prescribed by or in consultation with a cardiologist or a pulmonologist (initial/continuation) |
| **Coverage Duration** | Initial-6 months, Continuation-1 year |
| **Other Criteria** | INITIAL THERAPY-PULMONARY ARTERIAL HYPERTENSION (PAH) WHO GROUP 1-All of (A, B, C): A) right-heart catheterization to confirm the diagnosis, and B) Functional Class II or III, and C) One of (a or b): a)currently receiving at least two other PAH therapies from the following different pharmacologic categories, each for greater than or equal to 60 days: phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), and prostacyclins or b) currently receiving at least one other PAH therapy for greater than or equal to 60 days and is intolerant to combination therapy with a phosphodiesterase type 5 inhibitors (PDE5i), endothelin receptor antagonists (ERAs), soluble guanylate cyclase stimulator (sGCs), or prostacyclin. CONTINUATION THERAPY-PAH WHO GROUP 1-patient has had a right heart catheterization to confirm the diagnosis. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# XALKORI

**Products Affected**

- Xalkori

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Anaplastic large cell lymphoma/IMT-patients greater than or equal to 1 year of age. All other diagnoses-18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Metastatic non-small cell lung cancer-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease, as detected by an approved test and patients new to therapy must have a trial of Alecensa or Lorbrena prior to approval of Xalkori. Metastatic non-small cell lung cancer, approve if the patient has ROS1 rearrangement positive disease, as detected by an approved test. Anaplastic Large Cell Lymphoma-approve if the patient has anaplastic lymphoma kinase (ALK)-positive disease AND (i or ii): (i) the medication is used for palliative-intent therapy, or (ii) pt has relapsed or refractory disease. Histiocytic neoplasm-approve if the patient has ALK rearrangement/fusion-positive disease and meets one of the following criteria (i, ii, or iii): (i. Patient has Langerhans cell histiocytosis, OR ii. Patient has Erdheim-Chester disease OR iii. Patient has Rosai-Dorfman disease. NSCLC with MET mutation-approve if the patient has high level MET amplification or MET exon 14 skipping mutation. Inflammatory Myofibroblastic Tumor-approve if the patient has ALK positive disease and the patient has advanced, recurrent or metastatic disease or the tumor is inoperable. Melanoma, cutaneous-approve if the patient has ALK fusion disease or ROS1 fusion disease. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | NSCLC with high level MET amplification or MET Exon 14 skipping mutation, Histiocytic neoplasms, melanoma, cutaneous. |

| PA Criteria | Criteria Details |
|---|---|
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# XDEMVY

**Products Affected**

- Xdemvy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 6 months |
| **Other Criteria** | |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# XERMELO

**Products Affected**

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# XIFAXAN

**Products Affected**

- Xifaxan oral tablet 550 mg

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | Hepatic encephalopathy, irritable bowel syndrome with diarrhea - 18 years of age or older. |
| **Prescriber Restrictions** | Pouchitis - prescribed by or in consultation with a gastroenterologist |
| **Coverage Duration** | Enceph-6 mo, IBS w/diarrhea-14 days, intest bact overgrowth-14 days, Pouchitis - 1 year |
| **Other Criteria** | Hepatic Encephalopathy-approve if the patient has previously had overt hepatic encephalopathy and the requested medication will be used concomitantly with lactulose, unless the patient has a contraindication or significant intolerance to treatment with lactulose. Irritable bowel syndrome with diarrhea-approve. Small intestine bacterial overgrowth-approve if the diagnosis has been confirmed by a glucose hydrogen breath test, lactulose hydrogen breath test, or small bowel aspiration and culture. Chronic antibiotic-dependent pouchitis- approve if patient meets all of (a, b, c and d): a) recurrent pouchitis (Note: recurrent pouchitis is typically considered history of at least 3 pouchitis episodes within a 12 month period), and b) episodes of pouchitis respond to antibiotic therapy but relapse shortly after antibiotic discontinuation, and c) alternative causes of recurrent pouchitis have been ruled out, and d) has tried long-term antibiotic therapy trials (at least 4 weeks) of BOTH ciprofloxacin and metronidazole for remission maintenance. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Small intestine bacterial overgrowth, chronic antibiotic-dependent pouchitis |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | Yes |

# XOLAIR

**Products Affected**

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# XOSPATA

**Products Affected**

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, FLT3-mutation status |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | AML - approve if the disease is FLT3-mutation positive as detected by an approved test. Lymphoid, Myeloid Neoplasms-approve if the patient has eosinophilia and the disease is FLT3-mutation positive as detected by an approved test. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Lymphoid, Myeloid Neoplasms |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# XPOVIO

**Products Affected**

- Xpovio

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis, prior therapies |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Multiple Myeloma-Approve if the patient meets the following (A and B): A) The medication will be taken in combination with dexamethasone AND B) Patient meets one of the following (i, ii, or iii): i. Patient has tried at least four prior regimens for multiple myeloma OR ii. Patient meets both of the following (a and b): a) Patient has tried at least two prior regimens for multiple myeloma AND b) The medication will be taken in combination with Pomalyst (pomalidomide) OR iii. Patient meets both of the following (a and b): a) Patient has tried at least one prior regimen for multiple myeloma AND b) The medication will be taken in combination with bortezomib, Darzalex (daratumumb infusion), Darzlaex Faspro (daratumumab and hyaluronidase-fihj injection), or Kyprolis (carfilzomib intravenous infusion). Note:  Examples of prior regimens include Darzalex (daratumumab intravenous infusion)/bortezomib/lenalidomide/dexamethasone, bortezomib/lenalidomide/dexamethasone, Kyprolis (carfilzomib infusion)/lenalidomide/dexamethasone, Darzalex (daratumumab injection)/bortezomib or Kyprolis/dexamethasone, or other regimens containing a proteasome inhibitor, immunomodulatory drug, and/or anti-CD38 monoclonal antibody. Diffuse large B-cell lymphoma Note:this includes patients with histologic transformation of indolent lymphomas to diffuse large B-cell lymphoma)-approve if the patient has tried at least two prior therapies. B-Cell lymphoma-approve if (A and B): A) pt has high-grade B-cell lymphoma or HIV-related B-cell lymphoma or post-transplant lymphoproliferative disorders and B) has tried at least two prior therapies. |

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Treatment of multiple myeloma in combination with daratumumb or pomalidomide, B-cell lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# XTANDI

**Products Affected**

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis for which Xtandi is being used. |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |
| **Other Criteria** | Prostate cancer-castration-resistant [Metastatic or Non-metastatic] and Prostate cancer-metastatic, castration sensitive-approve if Xtandi will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog [for example: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets)] or if the patient has had a bilateral orchiectomy. Prostate cancer- Non-Metastatic, Castration-Sensitive - approve if pt has biochemical recurrence and is at high risk for metastasis. [Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time less than or equal to 9 months.] |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# XYREM

**Products Affected**

- sodium oxybate

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | Concomitant use with Xywav, Wakix or Sunosi |
| **Required Medical Information** | Medication history (as described in Other Criteria field) |
| **Age Restrictions** | 7 years and older |
| **Prescriber Restrictions** | Prescribed by a sleep specialist physician or a Neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | For Excessive daytime sleepiness (EDS) in patients with narcolepsy - narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Patients requesting sodium oxybate who are 18 years or older-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextroamphetamine), modafinil, or armodafinil. Patients less than 18 years old requesting sodium oxybate-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dextramphetamine) or modafinil. Cataplexy treatment in patients with narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZEJULA

**Products Affected**

- Zejula oral tablet

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Ovarian, fallopian tube, or primary peritoneal cancer, maintenance therapy - approve if the patient is in complete or partial response after platinum-based chemotherapy regimen and if the patient is new to therapy they must have a trial of Lynparza prior to approval of Zejula. Patients who have had a complete or partial response to first-line platinum based chemotherapy and do not have BRCA altered disease are not required to try Lynparza. Uterine leiomyosarcoma- approve if the patient has BRCA2-altered disease and has tried one systemic regimen. In addition, patients new to therapy must have a trial of Lynparza prior to approval of Zejula. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Uterine Leiomyosarcoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZELBORAF

**Products Affected**

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZOLINZA

**Products Affected**

- Zolinza

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | Diagnosis |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | 1 year |
| **Other Criteria** | Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve. |
| **Indications** | All FDA-approved Indications. |
| **Off Label Uses** | |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ZTALMY

**Products Affected**

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZURZUVAE

**Products Affected**

- Zurzuvae

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | No |

# ZYDELIG

**Products Affected**

- Zydelig

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year |
| **Other Criteria** | CLL/SLL-approve if the patient has tried at least one Bruton tyrosine kinase inhibitor (examples: ibrutinib, zanubrutinib, acalabrutinib, pirtobrutinib) and at least one Venclexta (venetoclax)-based regimen. |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Small lymphocytic lymphoma |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZYKADIA

**Products Affected**

- Zykadia

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | UNDER CMS REVIEW |
| **Required Medical Information** | UNDER CMS REVIEW |
| **Age Restrictions** | UNDER CMS REVIEW |
| **Prescriber Restrictions** | UNDER CMS REVIEW |
| **Coverage Duration** | UNDER CMS REVIEW |
| **Other Criteria** | UNDER CMS REVIEW |
| **Indications** | UNDER CMS REVIEW |
| **Off Label Uses** | UNDER CMS REVIEW |
| **Part B Prerequisite** | No |
| **Prerequisite Therapy Required** | Yes |

# ZYTIGA

**Products Affected**

- abiraterone oral tablet 250 mg
- Abirtega

| PA Criteria | Criteria Details |
|---|---|
| **Exclusion Criteria** | |
| **Required Medical Information** | |
| **Age Restrictions** | 18 years and older |
| **Prescriber Restrictions** | |
| **Coverage Duration** | Authorization will be for 1 year. |

| PA Criteria | Criteria Details |
|---|---|
| **Other Criteria** | Prostate Cancer-Metastatic, Castration-Resistant (mCRPC)-Approve if abiraterone is being used in combination with prednisone or dexamethasone and the medication is used concurrently used with a gonadotropin-releasing hormone (GnRH) analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate cancer-metastatic, castration-sensitive (mCSPC)-approve if the medication is used in combination with prednisone and the medication is concurrently used with a GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Prostate Cancer - Regional Risk Group - Approve if the patient meets all of the following criteria (A, B, and C): A) abiraterone is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii ): i. abiraterone with prednisone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer-very-high-risk-group-approve if according to the prescriber the patient is in the very-high-risk group, the medication will be used in combination with prednisone, the medication will be used in combination with external beam radiation therapy and the patient meets one of the following criteria (i or ii): i. abiraterone is used in combination with a GnRH analog (see Note 1) OR ii. Patient has had a bilateral orchiectomy. Prostate cancer- radical prostatectomy or post radiation therapy-approve if patient meets (A, B, C and D): A) the medication is used in combination with prednisone, B) meets (i or ii): i) the patient has prostate specific antigen (PSA) persistence or recurrence following radical prostatectomy or ii) PSA recurrence or positive digital rectal examination (DRE) after radiation therapy, C) patient has pelvic recurrence or positive regional lymph nodes, and D) the medication will be used concurrently with GnRH analog (see Note 1) or the patient has had a bilateral orchiectomy. Salivary Gland Tumors- approve if (A, B and C): A) used in combination with prednisone, B) androgen receptor-positive (AR+) recurrent, unresectable or metastatic tumor, and C) used in combination with a GnRH analog (see Note 1). Note 1: examples of GnRH analogs are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets). |
| **Indications** | All FDA-approved Indications, Some Medically-accepted Indications. |
| **Off Label Uses** | Prostate Cancer-Regional Risk Group, Prostate cancer-very-high-risk group, Prostate cancer- radical prostatectomy or post radiation, Salivary Gland Tumors |
| **Part B Prerequisite** | No |

| PA Criteria | Criteria Details |
|---|---|
| **Prerequisite Therapy Required** | No |