# ACTIMMUNE (S)

## Products Affected

- Actimmune INJ 100MCG/0.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ADCIRCA (S)

## Products Affected

- Alyq
- Tadalafil TABS 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# ADEMPAS (S)

**Products Affected**

- Adempas

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH, CTEPH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH, CTEPH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH, CTEPH (Reauth): Patient demonstrates positive clinical response to therapy. |

# AFINITOR (S)

## Products Affected

- Everolimus TABS 10MG, 2.5MG, 5MG, 7.5MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# AFINITOR DISPERZ (S)

**Products Affected**

- Everolimus TBSO

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. TSC-associated partial-onset seizures: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# AIMOVIG (S)

## Products Affected

- Aimovig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraines (EM) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 8 migraine days per month. All Indications (initial): History of failure (after at least a two month trial), contraindication, or intolerance to two of the following preventive treatments for migraine from different mechanisms of action: a) Elavil (amitriptyline) or Effexor (venlafaxine), OR b) Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR c) Atenolol, propranolol, nadolol, timolol, or metoprolol, OR d) Candesartan, OR e) Lisinopril. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | EM, CM (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial): 6 months. EM, CM (reauth): 12 months. |

| | |
|---|---|
| **Other Criteria** | EM, CM (reauth): Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines). Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache. |

# AKEEGA (S)

**Products Affected**

- Akeega

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of prostate cancer. Disease is all of the following: a) metastatic, b) castration-resistant, and c) deleterious or suspected deleterious BRCA-mutated (BRCAm). Used in combination with prednisone. One of the following: a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog, or b) Patient has had a bilateral orchiectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ALDURAZYME (S)

**Products Affected**

- Aldurazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mucopolysaccharidosis I: confirmed diagnosis of Hurler or Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# ALECENSA (S)

**Products Affected**

- Alecensa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

**Products Affected**

- Prolastin-c

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Alpha-1 antitrypsin (AAT) deficiency (initial): Diagnosis of congenital AAT deficiency. Diagnosis of emphysema. Continued conventional treatment for emphysema (e.g., bronchodilators). One of the following: 1) PiZZ, PiZ(null), or Pi(null)(null) protein phenotypes (homozygous) OR 2) other rare AAT disease genotypes associated with pre-treatment serum AAT level less than 11 µM/L [e.g., Pi(Malton, Malton), Pi(SZ)]. Circulating pre-treatment serum AAT level less than 11 µM/L (which corresponds to less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry), unless the patient has a concomitant diagnosis of necrotizing panniculitis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | AAT deficiency (initial, reauth): 12 months |
| **Other Criteria** | AAT deficiency (reauth): Patient demonstrates positive clinical response to therapy. Continued conventional treatment for emphysema (e.g., bronchodilators). |

# ALUNBRIG (S)

**Products Affected**

- Alunbrig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# AMPYRA (S)

## Products Affected

- Dalfampridine Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | MS (Initial): 6 months. (Reauth): 12 months. |
| **Other Criteria** | MS (Reauth): Physician confirmation that the patient's walking improved with therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured). |

# ARFORMOTEROL (S)

## Products Affected

- Arformoterol Tartrate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Obstructive Pulmonary Disease (COPD): Diagnosis of COPD. Used for maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | COPD: 12 months. |
| **Other Criteria** | Subject to Part B vs. Part D review. |

# AUGTYRO (S)

**Products Affected**

- Augtyro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced, or b) metastatic. Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Diagnosis of solid tumors. Disease has neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1). Disease is one of the following: A) Locally advanced, B) Metastatic, or C) Unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: A) Disease has progressed following previous treatment (e.g., radiation therapy, systemic therapy, tyrosine kinase inhibitor [TKI]), or B) Disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All indications: 12 months. |
| **Other Criteria** | All indications: Approve for continuation of prior therapy. |

# AUSTEDO (S)

**Products Affected**

- Austedo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | Initial: 3 months. Reauth: 12 months |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |

# AYVAKIT (S)

**Products Affected**

- Ayvakit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gastrointestinal stromal tumor (GIST): Diagnosis of GIST. Disease is one of the following: unresectable or metastatic. Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including PDGFRA D842V mutations. Advanced Systemic Mastocytosis (AdvSM): Diagnosis of AdvSM. Patient has one of the following: a) aggressive systemic mastocytosis (ASM), b) systemic mastocytosis with an associated hematological neoplasm (SM-AHN), or c) mast cell leukemia (MCL). Indolent Systemic Mastocytosis (ISM): Diagnosis of ISM. Platelet count is greater than 5 x 1^9/L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# BAFIERTAM (S)

**Products Affected**

- Bafiertam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: a) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to two of the following disease-modifying therapies for MS: 1) Teriflunomide, 2) Gilenya (fingolimod), or 3) Brand Tecfidera/generic dimethyl fumarate, OR b) for continuation of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |

# BALVERSA (S)

**Products Affected**

- Balversa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Urothelial Carcinoma: Diagnosis of urothelial carcinoma (UC). Disease is one of the following: Locally advanced or Metastatic. Presence of susceptible fibroblast growth factor receptor (FGFR) 3 genetic alterations as detected by an U.S. Food and Drug Administration (FDA)-approved test (therascreen FGFR RGQ RT-PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed on or after at least one line of prior systemic therapy (e.g., chemotherapy). One of the following: 1) Patient had been treated with prior PD-1 inhibitor (e.g., Opdivo [nivolumab], Keytruda [pembrolizumab]) or PD-L1 inhibitor therapy (e.g., Bavencio [avelumab]) or 2) Patient is not a candidate for PD-1 or PD-L1 inhibitor therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# BENLYSTA (S)

## Products Affected

- Benlysta INJ 200MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine)]). Lupus Nephritis (init): Diagnosis of active lupus nephritis. Currently receiving standard of care treatment for active lupus nephritis (e.g., corticosteroids [e.g., prednisone] with mycophenolate or cyclophosphamide). |
| **Age Restrictions** | SLE (init): IV (vial), SC (autoinjector): Patient is 5 years of age or older, SC (prefilled syringe): Patient is 18 years of age or older. Lupus Nephritis (init): IV (vial): Patient is 5 years of age or older, SC (autoinjector, prefilled syringe): Patient is 18 years of age or older. |
| **Prescriber Restrictions** | SLE (init): Prescribed by or in consultation with a rheumatologist. Lupus Nephritis (init): Prescribed by or in consultation with a nephrologist or rheumatologist. |
| **Coverage Duration** | SLE, Lupus Nephritis (init, reauth): 6 months |
| **Other Criteria** | SLE, Lupus Nephritis (reauth): Patient demonstrates positive clinical response to therapy. |

# BESREMI (S)

**Products Affected**

- Besremi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of polycythemia vera as confirmed by all of the following: 1) One of the following: a) Hemoglobin greater than 16.5 g/dL for men or hemoglobin greater than 16.0 g/dL for women, b) Hematocrit greater than 49% for men or hematocrit greater than 48% for women, or c) Increased red cell mass, AND 2) Bone marrow biopsy showing hypercellularity for age with trilineage growth (panmyelosis) including prominent erythroid, granulocytic and megakaryocytic proliferation with pleomorphic, mature megakaryocytes, AND 3) One of the following: a) Presence of JAK2 or JAK2 exon 12 mutation or b) Subnormal serum erythropoietin level. For high-risk polycythemia vera only (patient greater than or equal to 60 years old and/or prior thrombosis history), trial and inadequate response, contraindication or intolerance to hydroxyurea. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# BOSULIF (S)

**Products Affected**

- Bosulif

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# BRAFTOVI (S)

## Products Affected

- Braftovi CAPS 75MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). Colorectal Cancer: One of the following diagnoses: Colon Cancer or Rectal Cancer. One of the following: 1) Unresectable or advanced disease or 2) Metastatic disease. Patient has received prior therapy. Cancer is BRAF V600E mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Erbitux (cetuximab). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Mektovi (binimetinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# BRIVIACT (S)

## Products Affected

- Briviact SOLN
- Briviact TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Partial-onset seizures: Diagnosis of partial-onset seizures. |
| **Age Restrictions** | Patient is 1 month of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# BRONCHITOL (S)

## Products Affected

- Bronchitol

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (initial): Diagnosis of CF. Patient has passed the Bronchitol Tolerance Test (BTT). |
| **Age Restrictions** | CF (initial): Patient is 18 years of age or older. |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a pulmonologist or specialist affiliated with a CF care center. |
| **Coverage Duration** | CF (initial): 6 months. CF (reauth): 12 months. |
| **Other Criteria** | CF (reauth): Patient demonstrates positive clinical response to therapy. |

# BRUKINSA (S)

**Products Affected**

- Brukinsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma (MCL): Diagnosis of relapsed or refractory MCL. Patient has received at least one prior therapy for MCL (e.g., chemotherapy). Waldenstrom's Macroglobulinemia (WM)/Lymphoplasmacytic Lymphoma (LPL): Diagnosis of WM/LPL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. Disease is relapsed or refractory. Patient has received at least one prior anti-CD20-based regimen for MZL (e.g., rituximab, obinutuzumab). Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of ONE of the following: CLL or SLL. Follicular Lymphoma (FL): Diagnosis of FL. Disease is relapsed or refractory. Used in combination with Gazyva (obinutuzumab). Patient has received at least two prior lines of systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CABLIVI (S)

**Products Affected**

- Cablivi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acquired thrombotic thrombocytopenic purpura (aTTP): Diagnosis of aTTP. First dose was/will be administered by a healthcare provider as a bolus intravenous injection. Used in combination with immunosuppressive therapy (e.g. rituximab, glucocorticoids). One of the following: 1) Used in combination with plasma exchange or 2) both of the following: patient has completed plasma exchange and less than 59 days have or will have elapsed beyond the last plasma exchange. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hematologist or oncologist. |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# CABOMETYX (S)

**Products Affected**

- Cabometyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. One of the following: a) Trial and failure, contraindication, or intolerance to Nexavar (sorafenib tosylate), or b) Patient has metastatic disease, or c) Patient has extensive liver tumor burden, or d) Patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or e) Disease is unresectable. Differentiated Thyroid Cancer (DTC): Diagnosis of DTC. Patient is 12 years of age or older. Disease has progressed following prior VEGFR-targeted therapy (e.g., Lenvima [lenvatinib], Nexavar [sorafenib]). Disease or patient is refractory to radioactive iodine treatment or ineligible. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CALQUENCE (S)

**Products Affected**

- Calquence

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CAPLYTA (S)

**Products Affected**

- Caplyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Schizophrenia: Diagnosis of schizophrenia. Trial and failure, contraindication, or intolerance to two of the following oral generic formulary atypical antipsychotic agents: asenapine, aripiprazole, olanzapine, paliperidone, quetiapine (IR or ER), risperidone, ziprasidone. Bipolar disorder: Diagnosis of bipolar I or II disorder (bipolar depression). Patient has depressive episodes associated with bipolar disorder. Used as monotherapy or as adjunctive therapy with lithium or valproate. Trial and failure, contraindication, or intolerance to quetiapine (IR or ER) or olanzapine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# CAPRELSA (S)

**Products Affected**

- Caprelsa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Thyroid Cancer: Diagnosis of one of the following: a) medullary thyroid cancer (MTC), or b) unresectable locally advanced MTC. Patient has symptomatic disease or progressive disease. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with oncologist or endocrinologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CAYSTON (S)

**Products Affected**

- Cayston

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs. |
| **Age Restrictions** | CF (Initial): 7 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CF (Initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |

# CERDELGA (S)

**Products Affected**

- Cerdelga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gaucher disease: Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test. |
| **Age Restrictions** | Gaucher disease: Patient is 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Gaucher disease: 12 months |
| **Other Criteria** | N/A |

# CHOLBAM (S)

**Products Affected**

- Cholbam

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of a peroxisomal disorder based on one of the following: a) an abnormal urinary bile acid analysis by mass spectrometry OR b) molecular genetic testing consistent with the diagnosis, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) will be used as an adjunctive treatment. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism. |
| **Coverage Duration** | All uses: 4 months (initial), 12 months (reauth). |
| **Other Criteria** | All uses (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement in liver function. |

# CICLOPIROX (S)

## Products Affected

- Ciclodan SOLN
- Ciclopirox Nail Lacquer

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | All of the following: 1) Patient does not have lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 target toenail, AND 5) Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 48 weeks. |
| **Other Criteria** | N/A |

# CINRYZE (S)

**Products Affected**

- Cinryze

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For prophylaxis against HAE attacks. Not used in combination with other approved treatments for prophylaxis against HAE attacks. |
| **Age Restrictions** | HAE (prophylaxis): Patient is 6 years of age or older |
| **Prescriber Restrictions** | HAE (prophylaxis): Prescribed by or in consultation with an immunologist or an allergist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# COLUMVI (S)

**Products Affected**

- Columvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of one of the following: 1) Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS), or 2) Large B-cell lymphoma (LBCL) arising from follicular lymphoma. Patient has had two or more lines of systemic therapy (e.g., chemotherapy). Patient will receive pretreatment with Gazyva (obinutuzumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# COMETRIQ (S)

**Products Affected**

- Cometriq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# COPIKTRA (S)

**Products Affected**

- Copiktra

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of CLL or SLL. Disease is relapsed or refractory. Trial and failure, contraindication, or intolerance to at least two prior therapies for CLL/SLL (e.g., Leukeran [chlorambucil], Gazyva [obinutuzumab], Arzerra [ofatumumab], Bendeka [bendamustine], Imbruvica [ibrutinib], Rituxan [rituximab], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CORLANOR (S)

## Products Affected

- Corlanor TABS
- Ivabradine Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic heart failure (CHF) (initial): Diagnosis of CHF. Patient has NYHA Class II, III, or IV symptoms. Patient has a left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm. Patient has a resting heart rate of greater than or equal to 70 beats per minute. Patient has been hospitalized for worsening HF in the previous 12 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) ACE inhibitor (e.g., captopril, enalapril, lisinopril), 2) ARB (e.g., candesartan, losartan, valsartan), or 3) ARNI (e.g., Entresto [sacubitril and valsartan]), B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. Dilated Cardiomyopathy (DCM) (initial): Diagnosis of heart failure due to DCM. Patient has NYHA Class II, III, or, IV symptoms. Patient is in sinus rhythm. Patient has an elevated heart rate. Trial and failure, contraindication or intolerance to one of the following: 1) Beta blocker (e.g., bisoprolol, metoprolol succinate extended release), 2) Angiotensin-converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), or 3) Diuretic Agent (e.g., spironolactone, furosemide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CHF, DCM (initial): Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | CHF, DCM (initial, reauth): 12 months |

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|---|---|
| **Other Criteria** | CHF, DCM (reauth): Patient demonstrates positive clinical response to therapy. |

# COSENTYX (S)

## Products Affected

- Cosentyx INJ 150MG/ML, 75MG/0.5ML
- Cosentyx Sensoready Pen
- Cosentyx Unoready

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. Non-radiographic axial spondyloarthritis (nr-axSpA, initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints.) Enthesitis-Related Arthritis (ERA) (Initial): Diagnosis of active ERA. nr-axSpA, ERA (Initial): Minimum duration of a one-month TF/C/I to two non-steroidal anti-inflammatory drugs (NSAIDs) (eg, ibuprofen, naproxen) at maximally tolerated doses. Hidradenitis suppurativa (HS) (Initial): Diagnosis of moderate to severe HS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA, ERA (initial): Prescribed by or in consultation with a rheumatologist. |

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|---|---|
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Psoriasis (Reauth): Patient demonstrates positive clinical response to therapy. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. ERA (Reauth): Patient demonstrates a positive clinical response to therapy as evidenced by at least one of the following: Reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. HS (Reauth): Patient demonstrates positive clinical response to therapy. |

# COSENTYX IV (S)

**Products Affected**

- Cosentyx INJ 125MG/5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Cosentyx SC (secukinumab), Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Otezla (apremilast), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Rinvoq (upadacitinib), or Xeljanz/XR (tofacitinib/ER), OR b) for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: a) TF/C/I to two of the following: Cosentyx SC, Enbrel, one formulary adalimumab product, Rinvoq, Xeljanz/XR, OR b) for continuation of prior therapy. Non-radiographic axial spondyloarthritis (nr-axSpA) (Initial): Dx of active nr-axSpA with objective signs of inflammation (eg, C-reactive protein [CRP] levels above the upper limit of normal and/or sacroiliitis on magnetic resonance imaging [MRI], indicative of inflammatory disease, but without definitive radiographic evidence of structural damage on sacroiliac joints). One of the following: a) TF/C/I to both of the following: Cosentyx SC and Rinvoq, OR b) for continuation of prior therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS, nr-axSpA (Initial): Prescribed by or in consultation with a rheumatologist. |
| **Coverage Duration** | All uses (Initial): 6 months. All uses (Reauth): 12 months |

| | |
|---|---|
| **Other Criteria** | PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the body surface area (BSA) involvement from baseline. AS, nr-axSpA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. |

# COTELLIC (S)

**Products Affected**

- Cotellic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib. Histiocytic Neoplasm: Diagnosis of histiocytic neoplasm. Used as monotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# CYLTEZO (S)

## Products Affected

- Cyltezo
- Cyltezo Starter Package For Crohns Disease/uc/hs
- Cyltezo Starter Package For Psoriasis
- Cyltezo Starter Package For Psoriasis/uveitis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |

| | |
|---|---|
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (HS) (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS, Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

# DALIRESP (S)

## Products Affected

- Roflumilast

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Obstructive Pulmonary Disease (COPD) (initial): Diagnosis of COPD. History of COPD exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission. Trial and failure, intolerance, or contraindication to two prior therapies for COPD (e.g., Combivent, Spiriva). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | COPD (init, reauth): 12 months |
| **Other Criteria** | COPD (reauth): Patient demonstrates positive clinical response to therapy. |

# DARAPRIM (S)

## Products Affected

- Pyrimethamine TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Toxoplasmosis: 1) Patient is using pyrimethamine for the active treatment of toxoplasmosis (e.g., toxoplasmic encephalitis, ocular toxoplasmosis), secondary prophylaxis of toxoplasmosis, or treatment of congenital toxoplasmosis OR 2) Patient is using pyrimethamine for the primary prophylaxis of toxoplasmosis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Requests for coverage of any pyrimethamine products for the treatment and/or prophylaxis of malaria are not authorized and will not be approved. The use of pyrimethamine for the treatment and/or prophylaxis of malaria is not recommended by the Centers for Disease Control and Prevention (CDC). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Toxoplasmosis: Prescribed by or in consultation with an infectious disease specialist |
| **Coverage Duration** | Toxoplasmosis: 12 months |
| **Other Criteria** | N/A |

# DARZALEX FASPRO (S)

**Products Affected**

- Darzalex Faspro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Both of the following: Used as monotherapy and One of the following: i) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (e.g., lenalidomide [Revlimid], thalidomide [Thalomid]) or ii) patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Both of the following: used in combination with one of the following treatment regimens: lenalidomide and dexamethasone, bortezomib and dexamethasone, or carfilzomib and dexamethasone, AND patient has received at least one prior therapy (e.g., bortezomib [Velcade], carfilzomib [Kyprolis], ixazomib [Ninlaro], lenalidomide [Revlimid], thalidomide [Thalomid). OR C) Both of the following: used in combination with both pomalidomide and dexamethasone, AND patient has received at least one prior line of therapy including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]). Newly Diagnosed MM: Newly diagnosed MM. One of the following: A) Both of the following: patient is ineligible for autologous stem cell transplant AND one of the following: 1) used in combination with all of the following: bortezomib, melphalan, and prednisone or 2) used in combination with both of the following: lenalidomide and dexamethasone. OR B) Both of the following: patient is eligible for autologous stem cell transplant AND used in combination with all of the following: bortezomib, thalidomide, and dexamethasone. Light Chain (AL) Amyloidosis: Newly diagnosed light chain (AL) amyloidosis. Used in combination with all of the following: bortezomib, cyclophosphamide, and dexamethasone. All of the following: patient does not have New York Association (NYHA) Class IIIB disease, patient does not have NYHA class IV disease, and patient does not have Mayo Stage IIIB disease. |
| **Age Restrictions** | N/A |

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|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# DAURISMO (S)

**Products Affected**

- Daurismo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute myeloid leukemia (AML): Diagnosis of newly-diagnosed acute myeloid leukemia (AML) AND Used in combination with low-dose cytarabine AND One of the following: 1) Patient is greater than or equal to 75 years old, or 2) Patient has comorbidities that preclude the use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# DEFERASIROX (S)

**Products Affected**

- Deferasirox

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L. |
| **Age Restrictions** | Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo. |
| **Other Criteria** | Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC. |

# DEMSER (S)

## Products Affected

- Metyrosine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Preoperative preparation: Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Medication is being used for preoperative preparation. Trial and failure, contraindication, or intolerance to both of the following: a) alpha-adrenergic blocker (e.g., phenoxybenzamine, doxazosin, terazosin) AND b) beta-adrenergic blocker (e.g., propranolol, metoprolol). Treatment of pheochromocytoma (initial): Diagnosis of pheochromocytoma confirmed by one of the following biochemical testing: a) plasma free metanephrines OR b) urinary fractioned metanephrines. Patient with hormonally active (catecholamine excess) pheochromocytoma. One of the following: a) patient is not a candidate for surgery OR b) chronic treatment due to malignant pheochromocytoma. Patient has not reached normotension after treatment with a selective alpha-1-adrenergic blocker (e.g., doxazosin, terazosin) and beta-adrenergic blocker (e.g., propranolol, metoprolol). Medication will not be used to control essential hypertension. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Preop prep: Prescribed by or in consultation with an endocrinologist OR Endocrine surgeon. Pheochromocytoma (initial): Prescribed by or in consultation with endocrinologist OR provider who specializes in the management of pheochromocytoma. |
| **Coverage Duration** | Preop prep: 4 wks. Treatment of pheo (initial): 6 months, (reauth): 12 months. |
| **Other Criteria** | Treatment of pheochromocytoma (reauth): Patient demonstrates positive clinical response to therapy (e.g., decreased frequency and severity of hypertensive attacks). |

# DIACOMIT (S)

**Products Affected**

- Diacomit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of seizures associated with Dravet syndrome (DS). Used in combination with clobazam. Patient weighs 7kg or more. |
| **Age Restrictions** | Patient is 6 months of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# DOPTELET (S)

**Products Affected**

- Doptelet

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Thrombocytopenia Prior to Planned Procedure (TPPP): Diagnosis (dx) of thrombocytopenia. Patient has chronic liver disease and is scheduled to undergo a procedure. Baseline platelet count is less than 50,000/mcL. Chronic Immune Thrombocytopenia (ITP) (initial): Diagnosis of chronic immune (idiopathic) thrombocytopenic purpura (ITP) or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ITP (initial): Prescribed by or in consultation with a hematologist/oncologist. |
| **Coverage Duration** | TPPP: 1 month. ITP (initial, reauth): 12 months |
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. |

# DULERA (S)

**Products Affected**

- Dulera

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (initial): Diagnosis of asthma. Trial and failure, contraindication (e.g., safety concerns, not indicated for patient's age), or intolerance to Breo Ellipta (fluticasone furoate and vilanterol trifenatate). |
| **Age Restrictions** | Initial: Patient is 5 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Asthma (reauthorization): Patient demonstrates positive clinical response to therapy. |

# DUPIXENT (S)

## Products Affected

- Dupixent

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Eosinophilic Asthma (EA) (init): Dx of mod to severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-tx) peripheral blood eosinophil level greater than or equal to 150 cells/ml. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (eg, prednisone) within the past 12 mo, 2) Prior asthma-related hospitalization within the past 12 mo. Corticosteroid Dependent Asthma (CDA) (init): Dx of mod to severe asthma. Patient is currently dependent on oral corticosteroids for the treatment of asthma. EA, CDA (init): One of the following: 1) Both of the following: a) Patient is 6 years of age or older but less than 12 years of age b) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Medium-dose inhaled corticosteroid (eg, greater than 100 – 200 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]) or ii) One medium dosed combination ICS/LABA product (eg, Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]) OR 2) Patient is 12 years of age or older and Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [eg, LTRA [eg, montelukast], LABA [eg, salmeterol], LAMA [eg, tiotropium]), OR b) One maximally-dosed combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)]. |
| **Age Restrictions** | AD (initial): Patient is 6 months or age or older. CRSwNP, PN: no age restriction. EoE (initial): Patient is at least 1 year of age. |

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|---|---|
| **Prescriber Restrictions** | AD, Prurigo Nodularis (PN) (Initial): Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist. Asthma (initial, reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist. CRSwNP (initial, reauth): Prescribed by or in consultation with an otolaryngologist, allergist/immunologist, or pulmonologist. EoE (initial): Prescribed by or in consultation with a gastroenterologist or allergist/immunologist. |
| **Coverage Duration** | CRSwNP, EoE (Init/Reauth): 12 months. Asthma, AD, PN (Init): 6 mo. Asthma, AD, PN (reauth): 12 mo. |

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|---|---|
| **Other Criteria** | Chronic rhinosinusitis with nasal polyposis (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for CRSwNP. Eosinophilic esophagitis (EoE) (initial): Dx of EoE. Patient has symptoms of esophageal dysfunction (eg, dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain). Patient has at least 15 intraepithelial eosinophils per high power field (HPF). Other causes of esophageal eosinophilia have been excluded. Patient weighs at least 15 kg. Trial and failure, contraindication, or intolerance to at least an 8-week trial of one of the following: proton pump inhibitors (eg, pantoprazole, omeprazole) or topical (esophageal) corticosteroids (eg, budesonide, fluticasone). PN (init): Diagnosis of PN. TF/C/I to one medium or higher potency topical corticosteroid. Atopic dermatitis (AD) (init): Diagnosis (dx) of mod to severe AD. One of the following: a) Involvement of at least 10% body surface area (BSA), or b) SCORing Atopic Dermatitis (SCORAD) index value of at least 25. Trial and failure of a minimum 30-day supply (14-day supply for topical corticosteroids), contraindication (eg, safety concerns, not indicated for patient's age/weight), or intolerance to at least one of the following: a) Medium or higher potency topical corticosteroid, b) Pimecrolimus cream, c) Tacrolimus ointment, or d) Eucrisa (crisaborole) ointment. AD (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. EA (reauth): Patient demonstrates positive clinical response to therapy. CDA, PN, CRSwNP (reauth): Patient demonstrates a positive clinical response to therapy. EA, CDA (reauth): Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] (e.g., montelukast), long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications. CRSwNP (reauth): Used in combination with another agent for CRSwNP. EoE (reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement of at least one of the following from baseline: symptoms (eg, dysphagia, food impaction, chest pain, heartburn), histologic measures (eg, esophageal intraepithelial eosinophil count), or endoscopic measures (eg, edema, furrows, exudates, rings, strictures). |

# ELAPRASE (S)

**Products Affected**

- Elaprase

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II)) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# EMGALITY (S)

**Products Affected**

- Emgality

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraines (EM) (120 mg/mL strength only) (initial): Diagnosis of EM. Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (120 mg strength/mL only) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 8 migraine days per month. Episodic Cluster Headache (ECH) (100 mg/mL strength only) (initial): Diagnosis of episodic cluster headache. Patient has experienced at least 2 cluster periods lasting from 7 days to 365 days, separated by pain-free periods lasting at least three months. Medication will not be used in combination with another injectable CGRP inhibitor. EM, CM (120 mg/mL strength only) (initial): History of failure (after at least a two month trial), contraindication, or intolerance to two of the following preventive treatments for migraine from different mechanisms of action: a) Elavil (amitriptyline) or Effexor (venlafaxine), OR b) Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR c) Atenolol, propranolol, nadolol, timolol, or metoprolol, OR d) Candesartan, OR e) Lisinopril. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | EM, CM, ECH (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (initial): 6 months. ECH (initial): 3 months. EM, CM, ECH (reauth): 12 months. |

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| **Other Criteria** | EM, CM (120 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines). Use of acute migraine medications (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] [e.g., ibuprofen, naproxen], triptans [e.g., eletriptan, rizatriptan, sumatriptan]) has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (120 mg/mL strength only) (reauth): Patient continues to be monitored for medication overuse headache. ECH (100 mg/mL strength only) (reauth): Patient has experienced a positive response to therapy, demonstrated by a reduction in headache frequency and/or intensity. Medication will not be used in combination with another injectable CGRP inhibitor. |

# EMPAVELI (S)

**Products Affected**

- Empaveli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Paroxysmal Nocturnal Hemoglobinuria (PNH) (initial): Diagnosis of PNH. Trial and failure, contraindication, or intolerance to Ultomiris (ravulizumab). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PNH (initial, reauth): 12 months |
| **Other Criteria** | PNH (reauth): Patient demonstrates positive clinical response to therapy (e.g., improvement in hemoglobin level, hemoglobin stabilization, decrease in the number of red blood cell transfusions). |

# ENBREL (S)

## Products Affected

- Enbrel
- Enbrel Mini
- Enbrel Sureclick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month trial and failure, contraindication, or intolerance to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA (initial), PJIA (initial), AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |

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|---|---|
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. |

# ENDARI (S)

## Products Affected

- Endari
- L-glutamine PACK

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. Patient has had 2 or more painful sickle cell crises within the past 12 months. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Sickle cell disease (initial, reauth): 12 months |
| **Other Criteria** | Sickle cell disease (reauth): Patient demonstrates positive clinical response to therapy. |

# ENJAYMO (S)

**Products Affected**

- Enjaymo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of cold agglutinin disease (CAD) based on ALL of the following: a) Presence of chronic hemolysis (e.g., bilirubin level above the normal reference range, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count), b) Positive polyspecific direct antiglobulin test (DAT), c) Monospecific DAT strongly positive for C3d, d) Cold agglutinin titer greater than or equal to 64 measured at 4 degree celsius, e) Direct antiglobulin test (DAT) result for Immunoglobulin G (IgG) of 1+ or less. Patient does not have cold agglutinin syndrome secondary to other factors (e.g., overt hematologic malignancy, primary immunodeficiency, infection, rheumatologic disease, systemic lupus erythematosus or other autoimmune disorders). Baseline hemoglobin level less than or equal to 10.0 gram per deciliter (g/dL). One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months |

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|---|---|
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy as evidenced by ALL of the following: a) The patient has not required any blood transfusions after the first 5 weeks of therapy with Enjaymo AND b) Hemoglobin level greater than or equal to 12 gram per deciliter (g/dL) or increased greater than or equal to 2 g/dL from baseline. One of the following: a) Prescribed dose will not exceed 6,500 mg on day 0, 7, and every 14 days thereafter for patients weighing between 39 kg to less than 75 kg OR b) Prescribed dose will not exceed 7,500 mg on day 0, 7, and every 14 days thereafter for patients for patients weighing 75 kg or greater. |

# EPIDIOLEX (S)

**Products Affected**

- Epidiolex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Lennox-Gastaut syndrome (LGS): Diagnosis of seizures associated with LGS. Trial of, contraindication, or intolerance to two formulary anticonvulsants (e.g., topiramate, lamotrigine, valproate). Dravet syndrome (DS): Diagnosis of seizures associated with DS. Tuberous sclerosis complex (TSC): Diagnosis of seizures associated with TSC. |
| **Age Restrictions** | LGS, DS, TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | LGS, DS, TSC: Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# EPKINLY (S)

**Products Affected**

- Epkinly

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of one of the following: 1) Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, 2) Diffuse large B-cell lymphoma (DLBCL) arising from indolent lymphoma, or 3) High grade B-cell lymphoma. Patient has had two or more lines of systemic therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# EPOETIN ALFA (S)

## Products Affected

- Procrit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is receiving chemo. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon/peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 36% or Hgb less than 12 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo. |
| **Other Criteria** | Subject to ESRD review. CKD (Reauth): Dx of CKD. One of the following: 1) Most recent or average (avg) Hct over 3 months is 33% or less (Hgb is 11 g/dL or less) for patients on dialysis, without ESRD, 2) Most recent or avg Hct over 3 mo is 30% or less (Hgb 10 g/dL or less) for patients not on dialysis, OR 3) Most recent or avg Hct over 3 mo is 36% or less (Hgb 12 g/dL or less) for pediatric patients. Patient demonstrates positive clinical response to therapy from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Patient demonstrates positive clinical response to therapy from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Patient demonstrates positive clinical response to therapy from pre-treatment level. Patient is receiving chemo. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates positive clinical response to therapy from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Patient demonstrates a positive clinical response to therapy from pre-treatment level. Off-label uses (except MDS, HCV): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores. |

# EPOPROSTENOL (S)

## Products Affected

- Epoprostenol Sodium

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH (Initial): 6 months. (Reauth): 12 months |
| **Other Criteria** | Subject to Part B vs D review. PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# ERIVEDGE (S)

**Products Affected**

- Erivedge

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ERLEADA (S)

**Products Affected**

- Erleada

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ESBRIET (S)

## Products Affected

- Pirfenidone

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | IPF (initial): Prescribed by or in consultation with a pulmonologist |
| **Coverage Duration** | initial, reauth: 12 months |
| **Other Criteria** | IPF (reauth): Patient demonstrates positive clinical response to therapy. |

# EUCRISA (S)

**Products Affected**

- Eucrisa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Atopic dermatitis (initial): Diagnosis of mild to moderate atopic dermatitis. Trial and failure, contraindication, or intolerance to one prescription strength topical corticosteroid (e.g., triamcinolone acetonide, fluocinolone acetonide), unless the affected area is sensitive (i.e., face, axillae, groin). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates a positive clinical response to therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity). |

# EVRYSDI (S)

## Products Affected

- Evrysdi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Spinal muscular atrophy (SMA) (initial): Diagnosis of spinal muscular atrophy (SMA) type I, II, or III. Both of the following: a) The mutation or deletion of genes in chromosome 5q resulting in one of the following: 1) Homozygous gene deletion or mutation (e.g., homozygous deletion of exon 7 at locus 5q13) or 2) Compound heterozygous mutation (e.g., deletion of SMN1 exon 7 [allele 1] and mutation of SMN1 [allele 2]) AND b) Patient has at least 2 copies of SMN2. Patient is not dependent on both of the following: 1) Invasive ventilation or tracheostomy and 2) Use of non-invasive ventilation beyond use for naps and nighttime sleep. At least one of the following exams (based on patient age and motor ability) has been conducted to establish baseline motor ability: Hammersmith Infant Neurological Exam Part 2 (HINE-2) (infant to early childhood), Hammersmith Functional Motor Scale Expanded (HFMSE), Revised Upper Limb Module (RULM) Test (Non ambulatory), Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), Motor Function Measure 32 (MFM-32) Scale, or Item 22 of the Bayley Scales of Infant and Toddler Development Third Edition (BSID-III). Patient is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) patient has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) patient has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | SMA (Initial, Reauth): Prescribed by or in consultation with a neurologist with expertise in the diagnosis and treatment of SMA |

| | |
|---|---|
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | SMA (Reauth): Patient demonstrates positive clinical response to therapy. Pt is not to receive concomitant chronic survival motor neuron (SMN) modifying therapy for the treatment of SMA (e.g., Spinraza). One of the following: a) pt has not previously received gene replacement therapy for the treatment of SMA (e.g., Zolgensma) or b) pt has previously received gene therapy for the treatment of SMA (e.g., Zolgensma) AND submission of medical records (e.g., chart notes) documenting that there has been an inadequate response to gene therapy (e.g., sustained decrease in at least one motor test score over a period of 6 months). |

# FABRAZYME (S)

**Products Affected**

- Fabrazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Fabry Disease (init): Diagnosis of Fabry disease. One of the following: a) detection of pathogenic mutations in the GLA gene by molecular genetic testing, b) deficiency in α-galactosidase A (α-Gal A) enzyme activity in plasma, isolated leukocytes, or dried blood spots (DBS), or c) significant clinical manifestations (e.g., neuropathic pain, cardiomyopathy, renal insufficiency, angiokeratomas, cornea verticillata). Fabrazyme will not be used in combination with Galafold (migalastat). |
| **Age Restrictions** | Fabry Disease (init): Patient is 2 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Fabry Disease (init, reauth): 12 months |
| **Other Criteria** | Fabry Disease (reauth): Patient demonstrates positive clinical response to therapy. Fabrazyme will not be used in combination with Galafold (migalastat). |

# FASENRA (S)

## Products Affected

- Fasenra
- Fasenra Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months, OR 2) Prior asthma-related hospitalization within the past 12 months. One of the following: 1) Both of the following: a) Patient is 6 years of age or older but less than 12 years of age b) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Medium-dose inhaled corticosteroid (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day) and Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) or ii) One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/ salmeterol 50mcg], Symbicort [budesonide 80mcg/ formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]) OR 2) Patient is 12 years of age or older and Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) and ii) additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]), OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)]. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | Asthma (Initial/Reauth): Prescribed by or in consultation with a pulmonologist or allergist/immunologist |
| **Coverage Duration** | Asthma (init): 6 months. Asthma (reauth): 12 months |
| **Other Criteria** | Asthma (Reauth): Patient demonstrates positive clinical response to therapy. Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications. |

# FENTANYL (S)

**Products Affected**

- Fentanyl Citrate Oral Transmucosal

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# FINTEPLA (S)

**Products Affected**

- Fintepla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Dravet Syndrome: Diagnosis of seizures associated with Dravet syndrome. Lennox-Gastaut Syndrome: Diagnosis of seizures associated with Lennox-Gastaut syndrome. |
| **Age Restrictions** | All Indications: Patient is 2 years of age or older. |
| **Prescriber Restrictions** | All Indications: Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | All Indications: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# FIRAZYR (S)

## Products Affected

- Icatibant Acetate
- Sajazir

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. Diagnosis has been confirmed by C1 inhibitor (C1-INh) deficiency or dysfunction (Type I or II HAE) as documented by one of the following: a) C1-INH antigenic level below the lower limit of normal OR b) C1-INH functional level below the lower limit of normal. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks. |
| **Age Restrictions** | Patient is 18 years of age or older |
| **Prescriber Restrictions** | Prescribed by or in consultation with an immunologist or an allergist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# FIRMAGON (S)

**Products Affected**

- Firmagon INJ 120MG/VIAL, 80MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# FOTIVDA (S)

**Products Affected**

- Fotivda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of renal cell carcinoma. Disease is one of the following: relapsed or refractory. Patient has received two or more prior systemic therapies (e.g., cabozantinib + nivolumab, lenvatinib + pembrolizumab, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# FRUZAQLA (S)

**Products Affected**

- Fruzaqla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of metastatic colorectal cancer. Patient has been previously treated with both of the following: A) Fluoropyrimidine-, oxaliplatin-, irinotecan-based chemotherapy, and B) Anti-VEGF biological therapy (e.g., bevacizumab, ramucirumab). One of the following: A) Patient does not have RAS wild type tumors, OR B) Both of the following: a) Patient has RAS wild type tumors, AND b) Trial and failure, contraindication, or intolerance to both of the following: 1) An anti-EGFR biological therapy (e.g., panitumumab, cetuximab), and 2) One of the following: i) Trifluridine/tipiracil or ii) Regorafenib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# GAMASTAN (S)

## Products Affected

- Gamastan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# GAVRETO (S)

**Products Affected**

- Gavreto

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Presence of metastatic rearranged during transfection (RET) gene fusion-positive tumor(s) as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Thyroid Cancer: Diagnosis of thyroid cancer. Disease is one of the following: advanced or metastatic. Disease has presence of rearranged during transfection (RET) gene fusion-positive tumor(s). Disease requires treatment with systemic therapy. One of the following: patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. |
| **Age Restrictions** | Thyroid Cancer: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# GILENYA (S)

**Products Affected**

- Fingolimod Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |

# GILOTRIF (S)

**Products Affected**

- Gilotrif

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy (e.g., cisplatin, carboplatin) and b) squamous NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# GLATIRAMER ACETATE (S)

**Products Affected**

- Glatiramer Acetate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |

# GLEEVEC (S)

## Products Affected

- Imatinib Mesylate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+)/BCR ABL-positive chronic myelogenous leukemia (CML) OR B) Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements OR G) Aggressive systemic mastocytosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All uses: Approve for continuation of prior therapy. |

# GLP1 (PREFERRED) (S)

## Products Affected

- Bydureon Bcise
- Byetta
- Mounjaro
- Ozempic
- Rybelsus
- Trulicity

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: One of the following: a) For patients requiring ongoing treatment for type 2 diabetes mellitus (T2DM), submission of medical records (e.g., chart notes) confirming diagnosis of T2DM, OR b) Submission of medical records (e.g., chart notes) confirming diagnosis of T2DM as evidenced by one of the following laboratory values: i) A1c greater than or equal to 6.5%, ii) fasting plasma glucose (FPG) greater than or equal to 126 mg/dL, or iii) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during OGTT (oral glucose tolerance test). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# GLYCOPYRROLATE TABLET (S)

**Products Affected**

- Glycopyrrolate TABS 1MG, 2MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | Initial, Reauth: 3 months. |
| **Other Criteria** | Reauth: One of the following: 1) Patient's peptic ulcer has not healed, OR 2) Patient has a new peptic ulcer. One of the following: 1) Patient is receiving concomitant treatment therapy with a proton-pump inhibitor (PPI) (e.g., lansoprazole, omeprazole), OR 2) Both of the following: a) Patient has a contraindication or intolerance to PPIs, and b) Patient is receiving concomitant treatment therapy with an H2-receptor antagonist (e.g., famotidine, nizatidine). Patient experienced a reduction in peptic ulcer symptoms while on therapy. |

# GROWTH HORMONE, PREFERRED (S)

## Products Affected

- Genotropin
- Genotropin Miniquick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | PGHD(initial):less than 4mo w/suspected GD based on clinical presentation (eg, persistent neonatal hypoglycemia, persistent/prolonged neonatal jaundice/elev bilirubin, male infant with microgenitalia, midline anatomical defects, failure to thrive),OR hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expctd adult ht not attained and doc of expctd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender assoc with growth rates unlikely to permit attainment of adult height in the normal range. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal. |

| | |
|---|---|
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by or in consultation with an endocrinologist. GFCRI: prescribed by or in consultation with an endocrinologist or nephrologist |
| **Coverage Duration** | All uses (initial, reauth): 12 months |
| **Other Criteria** | AGHD(initial):dx of AGHD with clin records supporting dx of childhood-onset GHD, or adult-onset GHD w/clin records doc hormone deficiency d/t hypothalamic-pituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT],glucagon,macimorelin) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]) or doc deficiency of 3 anterior pituitary hormones (prolactin,ACTH,TSH,FSH/LH) and IGF-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD,IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH,TSH,prolactin,FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,glucagon,macimorelin) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, glucagon, macimorelin) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [glucagon at or below 3mcg/L], [macimorelin less than 2.8 ng/mL 30, 45, 60 and 90 mins after admin]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD after 2 GH stim tests(ITT,glucagon,macimorelin), w/ 2 corresponding peak GH values [ITT at or below 5mcg/L],[glucagon at or below 3mcg/L],[macimorelin less than 2.8 ng/mL 30,45,60,90 mins after admin]. |

# HRM - MEGESTROL SUSPENSION

## Products Affected

- Megestrol Acetate SUSP 40MG/ML, 625MG/5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. |
| **Age Restrictions** | PA applies to patients 65 years or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# HRM - MEGESTROL TABLET

## Products Affected

- Megestrol Acetate TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. |
| **Age Restrictions** | PA applies to patients 65 years or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Applies to New Starts only. |

# HUMIRA (S)

## Products Affected

- Humira INJ 10MG/0.1ML, 20MG/0.2ML, 40MG/0.4ML, 40MG/0.8ML
- Humira Pediatric Crohns Disease Starter Pack INJ 0, 80MG/0.8ML
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-pediatric Uc Starter Pack
- Humira Pen-ps/uv Starter

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PsO (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |

| | |
|---|---|
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Hidradenitis suppurativa (HS), Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

# IBRANCE (S)

**Products Affected**

- Ibrance

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ICLUSIG (S)

**Products Affected**

- Iclusig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All uses: Approve for continuation of prior therapy. |

# IDHIFA (S)

**Products Affected**

- Idhifa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH2 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# IGALMI (S)

**Products Affected**

- Igalmi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following diagnoses: Schizophrenia or Bipolar I or II disorder. For the treatment of acute agitation. Trial and failure, contraindication or intolerance to at least two products used in acute agitation (e.g., olanzapine, ziprasidone). Patient is currently being managed with maintenance medication for their underlying disorder (e.g., aripiprazole, olanzapine, quetiapine, lithium, valproic acid). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Approve for continuation of prior therapy. |

# IMBRUVICA (S)

**Products Affected**

- Imbruvica

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids like prednisone or methylprednisolone, mycophenolate). |
| **Age Restrictions** | (cGVHD): Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Uses: 12 months |
| **Other Criteria** | All Uses: Approve for continuation of prior therapy. |

# INBRIJA (S)

**Products Affected**

- Inbrija

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's disease (PD) (initial): Diagnosis of PD. Patient is experiencing intermittent OFF episodes. Patient is currently being treated with carbidopa/levodopa. Trial and failure, contraindication or intolerance to two of the following: MAO-B inhibitor (e.g., rasagiline, selegiline), dopamine agonist (e.g., pramipexole, ropinirole), or COMT Inhibitor (e.g., entacapone). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PD (initial): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | PD (initial, reauth): 12 months |
| **Other Criteria** | PD (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with carbidopa/levodopa. |

# INCRELEX (S)

**Products Affected**

- Increlex

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an endocrinologist |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | (Reauth): Patient demonstrates positive clinical response to therapy. |

# INLYTA (S)

**Products Affected**

- Inlyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: (1) used as first-line treatment in combination with avelumab or pembrolizumab or (2) used after failure of one prior systemic therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# INQOVI (S)

**Products Affected**

- Inqovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome. Patient is intermediate-1, intermediate-2, or high-risk per the International Prognostic Scoring System (IPSS). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# INREBIC (S)

## Products Affected

- Inrebic

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelofibrosis: Diagnosis of one of the following: primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# INTRON A (S)

**Products Affected**

- Intron A

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# IRESSA (S)

## Products Affected

- Gefitinib

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ISTURISA (S)

**Products Affected**

- Isturisa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Patient is not a candidate for pituitary surgery, OR b) Pituitary surgery has not been curative for the patient. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Cushing's disease (initial, reauth): 12 months |
| **Other Criteria** | Cushing's disease (reauth): Patient demonstrates positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease). |

# ITRACONAZOLE CAPSULE (S)

**Products Affected**

- Itraconazole CAPS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Systemic Fungal Infection (SFI): Diagnosis of a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis). Fingernail Onychomycosis: Diagnosis of fingernail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 6-week supply), contraindication, or intolerance to oral terbinafine. Toenail Onychomycosis: Diagnosis of toenail onychomycosis as confirmed by one of the following: i) positive potassium hydroxide (KOH) preparation, ii) fungal culture, OR iii) nail biopsy. Trial and failure (of a minimum 12-week supply), contraindication, or intolerance to oral terbinafine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | SFI:6mo.Fingernail Onychomycosis:5wks.Toenail Onychomycosis:3mo. |
| **Other Criteria** | N/A |

# IVERMECTIN (S)

**Products Affected**

- Ivermectin TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Strongyloidiasis: Diagnosis of intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite Strongyloides stercoralis. Onchocerciasis: Diagnosis of onchocerciasis due to the nematode parasite Onchocerca volvulus. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Strongyloidiasis: 3 weeks. Onchocerciasis: 6 months. |
| **Other Criteria** | N/A |

# IVIG (S)

## Products Affected

- Bivigam INJ 5GM/50ML
- Privigen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborn and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. Continued in Other Criteria Section. |
| **Age Restrictions** | HIV (initial): patient is less than or equal to 12 years of age. |

| | |
|---|---|
| **Prescriber Restrictions** | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist). |
| **Coverage Duration** | 4 months: Solid organ transplant. 12 months: all other diagnoses. |
| **Other Criteria** | [D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barre syndrome. 3) Inflammatory myopathies (dermatomyositis or polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplant and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. All products: Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. For non-oncology renewal, the patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy. |

# IWILFIN (S)

## Products Affected

- Iwilfin

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of high-risk neuroblastoma (HRNB). Patient has shown at least a partial response to prior multiagent, multimodality therapy. Prior therapy included anti-GD2 immunotherapy (e.g., Danyelza [naxitamab-gqgk], Unituxin [dinutuximab]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# JAKAFI (S)

**Products Affected**

- Jakafi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Myelofibrosis: Diagnosis of primary myelofibrosis, OR post-polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea. Acute graft versus host disease (aGVHD): Diagnosis of aGVHD. Disease is steroid-refractory. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD. Trial and failure of at least one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months. |
| **Other Criteria** | Approve for continuation of prior therapy. |

# JAYPIRCA (S)

**Products Affected**

- Jaypirca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mantle Cell Lymphoma (MCL): Diagnosis of MCL. Disease is one of the following: a) relapsed, or b) refractory. Patient has received at least two prior therapies for MCL, one of which is a Bruton Tyrosine Kinase (BTK) inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)]. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Diagnosis of one of the following: a) CLL, or b) SLL. Patient has received treatment for CLL/SLL with both of the following therapies: a) BTK inhibitor therapy [e.g., Calquence (acalabrutinib), Brukinsa (zanubrutinib)], and b) B-cell lymphoma 2 (BCL-2) inhibitor therapy [e.g., Venclexta (venetoclax)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# KALYDECO (S)

## Products Affected

- Kalydeco

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | CF (initial): Patient is 1 month of age or older. |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient demonstrates positive clinical response (i.e. improvement in lung function [percent predicted forced expiratory volume in one second (PPFEV1)], decreased number of pulmonary exacerbations) while on therapy. |

# KANJINTI (S)

**Products Affected**

- Kanjinti

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# KANUMA (S)

## Products Affected

- Kanuma

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of lysosomal acid lipase deficiency (e.g., LAL-D, Wolman Disease, Cholesteryl ester storage disease). Diagnosis was confirmed by one of the following: a) enzymatic blood test (e.g., dried blood spot test) demonstrating a deficiency of LAL enzyme activity, OR b) genetic testing for mutations in the Lipase A, Lysosomal Acid Type (LIPA) gene. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# KERENDIA (S)

**Products Affected**

- Kerendia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Urine albumin-to-creatinine ratio (UACR) greater than or equal to 30 mg/g. Estimated glomerular filtration rate (eGFR) greater than or equal to 25 mL/min/1.73 m2. Serum potassium level less than or equal to 5.0 mEq/L prior to initiating treatment. One of the following: 1) Minimum 30-day supply trial of a maximally tolerated dose and will continue therapy with one of the following: a) generic angiotensin-converting enzyme (ACE) inhibitor (e.g., benazepril, lisinopril), or b) generic angiotensin II receptor blocker (ARB) (e.g., losartan, valsartan), OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. One of the following: 1) Patient continues to be on a maximally tolerated dose of ACE inhibitor or ARB, OR 2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs. |

# KESIMPTA (S)

**Products Affected**

- Kesimpta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Sclerosis (MS) (Initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure (of a minimum 4-week supply), contraindication, or intolerance to one disease-modifying therapy for MS [e.g., Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Gilenya fingolimod)], OR 2) For continuation of prior therapy. Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (Initial, Reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (Initial, Reauth): 12 months |
| **Other Criteria** | MS (Reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapse, or disease progression). Not used in combination with another disease-modifying therapy for MS. Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ocrelizumab [Ocrevus]). |

# KINERET (S)

## Products Affected

- Kineret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: a) Either a trial and failure, contraindication, or intolerance (TF/C/I) to two of the following: Enbrel (etanercept), one formulary adalimumab product, Orencia (abatacept), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), or attestation demonstrating a trial may be inappropriate, OR b) For continuation of prior therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: 1) NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3) gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR 2) Both of the following: a) two of the following clinical symptoms: urticaria-like rash, cold/stress triggered episodes, sensorineural hearing loss, musculoskeletal symptoms (e.g., arthralgia, arthritis, myalgia), chronic aseptic meningitis, or skeletal abnormalities (e.g., epiphyseal overgrowth, frontal bossing) AND b) elevated acute phase reactants (eg, erythrocyte sedimentation rate [ESR], C-reactive protein [CRP], serum amyloid A [SAA]). Deficiency of Interleukin-1 Receptor Antagonist (DIRA): Diagnosis of DIRA. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician. |
| **Coverage Duration** | RA, NOMID (initial): 6 months, (reauth): 12 months. DIRA: 12 months. |

| | |
|---|---|
| **Other Criteria** | RA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. NOMID (reauth): Patient demonstrates positive clinical response to therapy. |

# KISQALI (S)

**Products Affected**

- Kisqali

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# KISQALI-FEMARA PACK (S)

## Products Affected

- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# KORLYM (S)

## Products Affected

- Korlym
- Mifepristone TABS 300MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial, reauth: 6 months |
| **Other Criteria** | Reauth: Patient demonstrates one of the following: patient has improved glucose tolerance while on therapy or patient has stable glucose tolerance while on therapy. |

# KOSELUGO (S)

**Products Affected**

- Koselugo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neurofibromatosis Type 1 (NF1): Diagnosis of NF1. Patient has plexiform neurofibromas that are both of the following: inoperable and causing significant morbidity (e.g., disfigurement, motor dysfunction, pain, airway dysfunction, visual impairment). Patient is able to swallow a capsule whole. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# KRAZATI (S)

## Products Affected

- Krazati

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: locally advanced or metastatic. Disease is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). Colorectal Cancer (CRC): Diagnosis of CRC. Disease is one of the following: locally advanced or metastatic. Tumor is KRAS G12C-mutated as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Erbitux (cetuximab). Patient has received prior treatment with ALL of the following: a) fluoropyrimidine-based chemotherapy, b) oxaliplatin-based chemotherapy, and c) irinotecan-based chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# KUVAN (S)

## Products Affected

- Sapropterin Dihydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | PKU (Init): 2 months (Reauth): 12 months |
| **Other Criteria** | PKU (reauth): Patient demonstrates positive clinical response to therapy. Patient will continue to have blood Phe levels measured periodically during therapy. |

# KYNMOBI (S)

## Products Affected

- Kynmobi
- Kynmobi Titration Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Parkinson's disease (PD) (Initial): Not used with any 5-HT3 antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron) |
| **Required Medical Information** | Parkinson's disease (PD) (Initial): Diagnosis of PD. Patient is experiencing acute intermittent hypomobility (defined as “off” episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Used in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PD (Initial): Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | PD (Initial, reauth): 12 months |
| **Other Criteria** | PD (Reauth): Patient demonstrates positive clinical response to therapy. |

# LANREOTIDE (S)

## Products Affected

- Lanreotide Acetate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist. |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# LENVIMA (S)

## Products Affected

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Differentiated thyroid cancer (DTC): Diagnosis of DTC. Renal Cell Carcinoma (RCC): Diagnosis of RCC. One of the following: 1) Both of the following: a) Used as first-line treatment and b) Used in combination with Keytruda (pembrolizumab), or 2) Both of the following: a) Treatment follows one prior anti-angiogenic therapy and b) Used in combination with everolimus. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Endometrial Carcinoma (EC): Diagnosis of advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). Patient has disease progression following systemic therapy. Used in combination with Keytruda (pembrolizumab) therapy. Patient is not a candidate for curative surgery or radiation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LIDOCAINE TOPICAL (S)

## Products Affected

- Lidocaine OINT 5%
- Lidocaine/prilocaine CREA
- Premium Lidocaine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# LIDODERM (S)

**Products Affected**

- Lidocaine PTCH 5%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Post-herpetic neuralgia: Diagnosis of post-herpetic neuralgia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# LIVMARLI (S)

## Products Affected

- Livmarli

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Alagille syndrome (ALGS) (initial): Both of the following: a) Diagnosis of ALGS, and b) Molecular genetic testing confirms mutations in the JAG1 or NOTCH2 gene. Patient is experiencing moderate to severe cholestatic pruritus. Patient has had an inadequate response to one of the following treatments used for the relief of pruritus: a) Ursodeoxycholic acid (e.g., Ursodiol), b) Antihistamines (e.g., diphenhydramine, hydroxyzine), c) Rifampin, or d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol). Progressive Familial Intrahepatic Cholestasis (PFIC) (init): Both of the following: a) Diagnosis of PFIC, and b) Molecular genetic testing confirms mutations in the ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, or MYO5B gene. Patient is experiencing moderate to severe cholestatic pruritus. Patient has had an inadequate response to one of the following treatments used for the relief of pruritus: a) Ursodeoxycholic acid (e.g., Ursodiol), b) Antihistamines (e.g., diphenhydramine, hydroxyzine), c) Rifampin, or d) Bile acid sequestrants (e.g., Questran, Colestid, Welchol). |
| **Age Restrictions** | ALGS (initial): Patient is 3 months of age or older. PFIC (init): Patient is 12 months of age or older. |
| **Prescriber Restrictions** | All indications (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist. |
| **Coverage Duration** | ALGS (initial, reauth): 12 months. PFIC (init): 6 months, (reauth): 12 months. |
| **Other Criteria** | All indications (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduced bile acids, reduced pruritus severity score). |

# LONSURF (S)

## Products Affected

- Lonsurf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND One of the following: Used as a single agent or Used in combination with bevacizumab AND trial and failure, contraindication, or intolerance to fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., bevacizumab)) AND One of the following: A) patient has RAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has RAS mutant tumors. Gastric/Gastroesophageal Junction Adenocarcinoma: Diagnosis of metastatic gastric cancer or diagnosis of metastatic gastroesophageal junction adenocarcinoma. Trial and failure, contraindication or intolerance to at least two of the following: fluropyrimidine-based chemotherapy (e.g. fluorouracil), Platinum-based chemotherapy (e.g., carboplatin, cisplatin, oxaliplatin), Taxane (e.g., docetaxel, paclitaxel) or irinotecan-based chemotherapy, HER2/neu-targeted therapy (e.g., trastuzumab) (if HER2 overexpression). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LOQTORZI (S)

**Products Affected**

- Loqtorzi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of nasopharyngeal carcinoma (NPC). Disease is one of the following: A) metastatic, or B) recurrent and locally advanced. One of the following: A) Both of the following: 1) Loqtorzi is being used as first line treatment, and 2) Loqtorzi is being used in combination with cisplatin and gemcitabine, or B) Both of the following: 1) Loqtorzi is being used as recurrent NPC treatment, and 2) Disease has progressed on or after a platinum containing chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LORBRENA (S)

**Products Affected**

- Lorbrena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LOTRONEX (S)

## Products Affected

- Alosetron Hydrochloride

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide]. |
| **Age Restrictions** | Initial: 18 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | IBS (initial): 12 weeks. IBS (reauth): 6 mo. |
| **Other Criteria** | IBS (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy (e.g., relief of IBS abdominal pain and discomfort, improvement in stool consistency and frequency, improvement as measured by the Global Improvement Scale). |

# LUMAKRAS (S)

**Products Affected**

- Lumakras

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is one of the following: a) locally advanced or b) metastatic. Presence of KRAS G12C-mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has received at least one prior systemic therapy (e.g., chemotherapy, immunotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LUMIZYME (S)

**Products Affected**

- Lumizyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Infantile Onset Pompe Disease (IOPD) (initial): Diagnosis of IOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 1% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., cardiomegaly, hypotonia, etc.). Late Onset Pompe Disease (LOPD) (initial): Diagnosis of LOPD (lysosomal acid alpha-glucosidase [GAA] deficiency) as confirmed by one of the following: 1) Absence or deficiency (less than 40% of the lab specific normal mean) of GAA enzyme activity in lymphocytes, fibroblasts, or muscle tissues as confirmed by an enzymatic assay, OR 2) Molecular genetic testing confirms mutations in the GAA gene. Presence of clinical signs and symptoms of the disease (e.g., respiratory distress, skeletal muscle weakness, etc.). |
| **Age Restrictions** | IOPD (initial): Patient is less than or equal to 12 months of age. LOPD (initial): Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | IOPD, LOPD (initial, reauth): 12 months |
| **Other Criteria** | IOPD, LOPD (reauth): Patient demonstrates positive clinical response to therapy. |

# LUPRON (S)

**Products Affected**

- Leuprolide Acetate INJ 1MG/0.2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate CA: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LUPRON DEPOT (S)

## Products Affected

- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID (e.g., diclofenac, ibuprofen, meloxicam, naproxen) and one oral contraceptive (e.g., norethindrone-ethinyl estradiol, estradiol and norethindrone). Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prostate CA: 12 mo. Endomet:6mo. UL (anemia):3 mo (fibroids):4 mo |
| **Other Criteria** | Approve for continuation of prior therapy. |

# LYNPARZA TABLET (S)

**Products Affected**

- Lynparza TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Breast cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Pancreatic adenocarcinoma: Diagnosis of pancreatic adenocarcinoma. Prostate cancer: Diagnosis of castration-resistant prostate cancer. All indications: Approve for continuation of prior therapy. |

# LYTGOBI (S)

**Products Affected**

- Lytgobi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of intrahepatic cholangiocarcinoma. Disease is one of the following: a) unresectable, b) locally advanced, or c) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangements. Patient has been previously treated (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a hepatologist, gastroenterologist, or oncologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# MARINOL (S)

## Products Affected

- Dronabinol

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CINV: 6 months. AIDS anorexia: 3 months. |
| **Other Criteria** | Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy. |

# MAVYRET (S)

## Products Affected

- Mavyret

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: 1) One of the following: a) Diagnosis of chronic hepatitis C (CHC), or b) Patient was not infected with hepatitis C virus prior to receiving an organ transplant, and patient received a liver or non-liver organ transplant from a donor with a diagnosis of CHC, 2) patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and 3) not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine. |
| **Coverage Duration** | 8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline. |
| **Other Criteria** | N/A |

# MEKINIST (S)

## Products Affected

- Mekinist

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E or V600K mutant type as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib).Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |

| | |
|---|---|
| **Other Criteria** | Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). Low-grade glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Tafinlar (dabrafenib). |

# MEKTOVI (S)

**Products Affected**

- Mektovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAF V600E or V600K mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib). Non-Small Cell Lung Cancer (NSCLC): Diagnosis of metastatic NSCLC. Cancer is BRAF V600E mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with Braftovi (encorafenib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# MIGRANAL (S)

**Products Affected**

- Dihydroergotamine Mesylate SOLN

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of migraine headaches with or without aura. Will be used for the acute treatment of migraine. One of the following: Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or contraindication to all triptans. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). |

# MS INTERFERONS (PREFERRED) (S)

## Products Affected

- Betaseron

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |

# NAGLAZYME (S)

**Products Affected**

- Naglazyme

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux-Lamy Syndrome). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | MPS VI: 12 months |
| **Other Criteria** | N/A |

# NERLYNX (S)

**Products Affected**

- Nerlynx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Early Stage Breast cancer: Diagnosis (dx) of early stage breast cancer. Advanced or Metastatic Breast Cancer: Dx of advanced or metastatic breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# NEULASTA (S)

## Products Affected

- Neulasta
- Neulasta Onpro Kit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). Treatment of FN: Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses: Prescribed by or in consultation with a hematologist/oncologist |
| **Coverage Duration** | ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx. |
| **Other Criteria** | N/A |

# NEXAVAR (S)

## Products Affected

- Sorafenib
- Sorafenib Tosylate TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of RCC. Hepatocellular carcinoma (HCC): Diagnosis of HCC. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease, metastatic disease, or unresectable disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Disease is symptomatic with distant metastases. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# NINLARO (S)

**Products Affected**

- Ninlaro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple myeloma: Diagnosis of multiple myeloma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# NORTHERA (S)

**Products Affected**

- Droxidopa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist |
| **Coverage Duration** | NOH (init): 1 month (reauth): 12 months |
| **Other Criteria** | NOH (reauth): Patient demonstrates positive clinical response to therapy. |

# NOXAFIL SUSPENSION (S)

## Products Affected

- Posaconazole SUSP

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Oropharyngeal Candidiasis (OPC): Diagnosis of OPC. One of the following: 1) Trial and failure, contraindication, or intolerance to fluconazole OR 2) Susceptibility results demonstrate resistance to fluconazole. |
| **Age Restrictions** | Prophylaxis of SFI, OPC: Patient is 13 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prophylaxis of SFI: 6 months. OPC: 1 month. |
| **Other Criteria** | N/A |

# NUBEQA (S)

**Products Affected**

- Nubeqa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or castration-recurrent prostate cancer. Hormone-sensitive prostate cancer (HSPC): Diagnosis of HSPC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CRPC, HSPC: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# NUEDEXTA (S)

## Products Affected

- Nuedexta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pseudobulbar affect (PBA) (initial): Diagnosis of PBA. Patient does not have any of the following contraindications: a) Concomitant use with other drugs containing quinidine, quinine, or mefloquine, b) History of Nuedexta, quinine, mefloquine or quinidine-induced thrombocytopenia, hepatitis, bone marrow depression, or lupus-like syndrome, c) Known hypersensitivity to dextromethorphan (e.g., rash, hives), d) Taking monoamine oxidase inhibitors (MAOIs) (e.g., phenelzine, selegiline, tranylcypromine) or have taken MAOIs within the preceding 14 days, e) Has prolonged QT interval, congenital long QT syndrome or a history suggestive of torsades de pointes, or has heart failure, f) Receiving drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine, pimozide), g) Has complete atrioventricular (AV) block without implanted pacemakers, or at high risk of complete AV block. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PBA (initial): Prescribed by or in consultation with one of the following specialists: neurologist, psychiatrist. |
| **Coverage Duration** | PBA (initial/reauth): 12 months |
| **Other Criteria** | PBA (reauth): Patient demonstrates clinical benefit from ongoing therapy as demonstrated by a decrease in inappropriate laughing or crying episodes. |

# NUPLAZID (S)

## Products Affected

- Nuplazid CAPS
- Nuplazid TABS 10MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# NURTEC (S)

## Products Affected

- Nurtec

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Treatment of Migraine (initial): Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines. |
| **Age Restrictions** | All Indications (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Acute Treatment (init): 3mo. Preventive Treatment (init): 6mo. All Indications (reauth): 12mo. |

| | |
|---|---|
| **Other Criteria** | Preventive Treatment of Episodic Migraine (EM) (initial): Both of the following: 1) Diagnosis of EM and 2) Patient has greater than or equal to 4 migraine days per month. History of failure (after at least a two month trial), contraindication, or intolerance to two of the following preventive treatments for migraine from different mechanisms of action: a) Elavil [amitriptyline] or Effexor [venlafaxine], b) Depakote/Depakote ER [divalproex sodium] or Topamax [topiramate], c) Atenolol, propranolol, nadolol, timolol, or metoprolol, d) Candesartan, e) Lisinopril. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. Acute Treatment of Migraine (reauth): Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines. Preventive Treatment of EM (reauth): Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines). Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |

# NUVIGIL (S)

## Products Affected

- Armodafinil

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: a) 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or b) both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), AND 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | OSA, SWD: Initial, Reauth: 6 mo. Narcolepsy: Initial, Reauth: 12 mo |

| | |
|---|---|
| **Other Criteria** | OSA, Narcolepsy (Reauth): Patient demonstrates positive clinical response to armodafinil therapy. SWD (Reauth): Patient demonstrates positive clinical response to armodafinil therapy. |

# ODOMZO (S)

**Products Affected**

- Odomzo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OFEV (S)

**Products Affected**

- Ofev

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Idiopathic pulmonary fibrosis (IPF) (initial): Diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF. Systemic sclerosis-associated interstitial lung disease (SSc-ILD) (initial): Diagnosis of SSc-ILD as documented by all of the following: a) exclusion of other known causes of ILD (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) One of the following: i) In patients not subjected to surgical lung biopsy, the presence of idiopathic interstitial pneumonia (eg, fibrotic nonspecific interstitial pneumonia [NSIP], usual interstitial pneumonia [UIP] and centrilobular fibrosis) pattern on HRCT revealing SSc-ILD or probable SSc-ILD, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing SSc-ILD or probable SSc-ILD. Chronic Fibrosing Interstitial Lung Diseases (ILDs) with a Progressive Phenotype (initial): 1) diagnosis of chronic fibrosing interstitial lung disease, AND 2) patient has a high-resolution computed tomography (HRCT) showing at least 10% of lung volume with fibrotic features, AND 3) disease has a progressive phenotype as observed by one of the following: decline of forced vital capacity (FVC), worsening of respiratory symptoms, or increased extent of fibrosis seen on imaging. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (initial): Prescribed by or in consultation with a pulmonologist |

| | |
|---|---|
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | IPF, SSc-ILD, Chronic Fibrosing ILDs with a Progressive Phenotype (reauth): Patient demonstrates positive clinical response to therapy. |

# OGSIVEO (S)

**Products Affected**

- Ogsiveo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of desmoid tumor. Patient requires systemic treatment. Disease is progressive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OJEMDA (S)

**Products Affected**

- Ojemda

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of pediatric low-grade glioma. Disease is relapsed or refractory. Disease has a BRAF fusion or rearrangement, or BRAF V600 mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OJJAARA (S)

**Products Affected**

- Ojjaara

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Patient has anemia. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ONUREG (S)

**Products Affected**

- Onureg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of acute myeloid leukemia (AML). Patient has received previous treatment with an intensive induction chemotherapy regimen (e.g., cytarabine + daunorubicin, cytarabine + idarubicin, etc.). Patient has achieved one of the following: a) first complete remission (CR) or b) complete remission with incomplete blood count recovery (CRi). Patient is not able to complete intensive curative therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OPDUALAG (S)

**Products Affected**

- Opdualag

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following diagnoses: unresectable melanoma or metastatic melanoma. Both of the following: patient is 12 years of age or older AND patient weighs at least 40 kg (88 lbs). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OPSUMIT (S)

**Products Affected**

- Opsumit

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# ORENCIA IV (S)

**Products Affected**

- Orencia INJ 250MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Acute graft versus host disease (aGVHD): Used for prophylaxis of aGVHD. Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor. Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT. Used in combination with both of the following: calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate. |
| **Age Restrictions** | aGVHD: Patient is 2 years of age or older |
| **Prescriber Restrictions** | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | RA, JIA, PsA (initial): 6 months, (reauth): 12 months. aGVHD: 2 months |

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|---|---|
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |

# ORENCIA SC (S)

## Products Affected

- Orencia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML
- Orencia Clickject

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | All uses (initial): 6 months, (reauth): 12 months |

| | |
|---|---|
| **Other Criteria** | RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |

# ORGOVYX (S)

**Products Affected**

- Orgovyx

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ORKAMBI (S)

**Products Affected**

- Orkambi TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by a U.S. Food and Drug Administration (FDA)-cleared cystic fibrosis mutation test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | CF (Initial): Patient is 6 years of age or older |
| **Prescriber Restrictions** | CF (initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |

# ORSERDU (S)

**Products Affected**

- Orserdu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Disease is advanced or metastatic. Disease is estrogen receptor (ER)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Presence of estrogen receptor (ESR1) mutation(s) as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease has progressed following at least one line of endocrine therapy [e.g., Faslodex (fulvestrant), Arimidex (anastrozole), Femara (letrozole), Aromasin (exemestane)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# OSMOLEX ER (S)

## Products Affected

- Osmolex Er

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Parkinson's Disease (PD) (initial): Diagnosis of Parkinson's disease. Trial and failure or intolerance to both of the following: A) amantadine immediate release AND B) one of the following: carbidopa-levodopa, MAO-B inhibitor (e.g., rasagiline, selegiline), or dopamine agonist (e.g., pramipexole, ropinirole). Drug-Induced Extrapyramidal Reactions (EPS) (initial): Patient is experiencing drug-induced extrapyramidal reactions. One of the following: A) Patient has persistent extrapyramidal symptoms despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR B) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Trial and failure or intolerance to amantadine immediate release. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PD (initial): Prescribed by or in consultation with a neurologist. EPS (initial): Prescribed by or in consultation with a neurologist or psychiatrist. |
| **Coverage Duration** | PD, EPS (initial, reauth): 12 months |
| **Other Criteria** | PD, EPS (Reauth): Patient demonstrates positive clinical response to therapy |

# OSPHENA (S)

**Products Affected**

- Osphena

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Dyspareunia (initial): Diagnosis of moderate to severe dyspareunia due to vulvar and vaginal atrophy associated with menopause. Vaginal dryness (initial): Diagnosis of moderate to severe vaginal dryness due to vulvar and vaginal atrophy associated with menopause. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses (Initial, reauth): 12 months |
| **Other Criteria** | Dyspareunia, Vaginal dryness (reauth): Patient demonstrates positive clinical response to therapy. |

# OTEZLA (S)

## Products Affected

- Otezla

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Psoriatic arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque psoriasis (initial): Diagnosis of plaque psoriasis. Oral ulcers associated with Behcet's Disease (Initial): Diagnosis of Behcet's Disease. Patient has active oral ulcers. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months. |
| **Other Criteria** | PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy. Oral ulcers associated with Behcet's Disease (reauth): Patient demonstrates positive clinical response to therapy (eg, reduction in pain from oral ulcers or reduction in number of oral ulcers). |

# OXBRYTA (S)

**Products Affected**

- Oxbryta TABS 300MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of Sickle Cell Disease. Patient demonstrates hemoglobin level that does not exceed 10.5 g/dL prior to therapy initiation. Trial and failure or inadequate response, contraindication, or intolerance to hydroxyurea. |
| **Age Restrictions** | Initial: Patient is 4 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: 1) Hematologist/Oncologist or 2) Specialist w/ expertise in the diagnosis and management of sickle cell disease. |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# PEGASYS (S)

## Products Affected

- Pegasys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Chronic Hepatitis C: Prescribed by or in consultation with one of the following: hepatologist, gastroenterologist, infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine |
| **Coverage Duration** | HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks. |
| **Other Criteria** | N/A |

# PEMAZYRE (S)

**Products Affected**

- Pemazyre

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is one of the following: unresectable locally advanced or metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. Myeloid/lymphoid neoplasms: Diagnosis of myeloid/lymphoid neoplasms (MLNs). Disease is relapsed or refractory. Disease has presence of a fibroblast growth factor receptor 1 (FGFR1) rearrangement. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# PHESGO (S)

## Products Affected

- Phesgo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | N/A |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# PIQRAY (S)

## Products Affected

- Piqray 200mg Daily Dose
- Piqray 250mg Daily Dose
- Piqray 300mg Daily Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast Cancer (BC): Diagnosis of advanced or metastatic BC. Disease is hormone receptor (HR)-positive, and human epidermal growth factor receptor 2 (HER2)-negative. Cancer is PIK3CA-mutated as detected by an FDA-approved test (therascreen PIK3CA RGQ PCR Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with fulvestrant. Disease has progressed on or after an endocrine-based regimen. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# POMALYST (S)

## Products Affected

- Pomalyst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Myeloma (MM): Diagnosis of MM. Kaposi sarcoma (KS): One of the following: 1) Diagnosis of AIDS-related KS, OR 2) Both of the following: a) Diagnosis of KS and b) Patient is HIV-negative. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# POSACONAZOLE TABLET (S)

## Products Affected

- Posaconazole Dr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prophylaxis of systemic fungal infections (SFI): Used as prophylaxis of invasive fungal infections caused by Aspergillus or Candida for one of the following conditions: 1) Patient is at high risk of infections due to severe immunosuppression from hematopoietic stem cell transplant (HSCT) with graft-versus-host disease (GVHD) or hematologic malignancies with prolonged neutropenia from chemotherapy OR 2) patient has a prior fungal infection requiring secondary prophylaxis. Treatment (Tx) of SFI: Used as treatment of systemic fungal infections caused by Aspergillus. |
| **Age Restrictions** | Prophylaxis of SFI: Patient is 2 years of age or older. Tx of SFI: Patient is 13 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Prophylaxis of SFI: 6 months. Tx of SFI: 3 months. |
| **Other Criteria** | N/A |

# PROMACTA (S)

## Products Affected

- Promacta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of one of the following: relapsed/refractory ITP, persistent ITP, or chronic ITP. Baseline platelet count is less than 30,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. Trial and failure, intolerance, contraindication to corticosteroids (e.g., prednisone, methylprednisolone), immunoglobulins [e.g., Gammagard, immune globulin (human)], or splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C-associated thrombocytpenia. One of the following: 1) Planning to initiate and maintain interferon-based treatment, or 2) currently receiving interferon-based treatment. First-line for severe aplastic anemia (SAA): Diagnosis of SAA. Used for first-line treatment (i.e., patient has not received prior immunosuppressive therapy). Used in combination with standard immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). Patient meets at least two of the following: 1) absolute neutrophil count less than 500/mcL, 2) platelet count less than 20,000/mcL, 3) absolute reticulocyte count less than 60,000/mcL. Refractory SAA (initial): Diagnosis of refractory severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Insufficient response to immunosuppressive therapy (e.g., horse antithymocyte globulin, cyclosporine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ITP and SAA: Prescribed by or in consultation with a hematologist/oncologist. Chronic hepatitis C associated thrombocytopenia: Prescribed by or in consultation with a hematologist/oncologist, gastroenterologist, hepatologist, infectious disease specialist, or HIV specialist certified through the American Academy of HIV Medicine. |

| | |
|---|---|
| **Coverage Duration** | ITP(init,reauth):12mo.HepC:3mo(init),12mo(reauth).1stline SAA:6mo.RefractSAA:16wk-init,12mo-reauth |
| **Other Criteria** | ITP (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding. Hepatitis C (reauth): One of the following: 1) For patients that started treatment with eltrombopag prior to initiation of treatment with interferon, eltrombopag will be approved when both of the following are met: a) Currently on antiviral interferon therapy for treatment of chronic hepatitis C and b) Documentation that the patient reached a threshold platelet count that allows initiation of antiviral interferon therapy with eltrombopag treatment by week 9, OR 2) For patients that started treatment with eltrombopag while on concomitant treatment with interferon, eltrombopag will be approved based on the following: Currently on antiviral interferon therapy for treatment of chronic hepatitis C. Refractory SAA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by an increase in platelet count. |

# PROVIGIL (S)

## Products Affected

- Modafinil TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Obstructive sleep apnea (OSA) (Initial): Diagnosis (dx) of OSA defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work disorder (SWD) (Initial):Dx of SWD confirmed by one of the following: 1) Symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, OR 2) A sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). Confirmation that no other medical conditions or medications are causing the symptoms of excessive sleepiness or insomnia. Narcolepsy (initial): Dx of narcolepsy as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy. Idiopathic Hypersomnia (Initial): Diagnosis of idiopathic hypersomnia as confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Narcolepsy: Init, Reauth: 12 mo. All other indications: Init, Reauth: 6 mo. |
| **Other Criteria** | OSA, Narcolepsy, Idiopathic Hypersomnia (Reauth): Patient demonstrates positive clinical response to modafinil therapy. SWD (Reauth): Patient demonstrates positive clinical response to modafinil therapy. MS Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Depression (reauth): Patient demonstrates positive clinical response to modafinil therapy. Used as adjunctive therapy. |

# PULMOZYME (S)

**Products Affected**

- Pulmozyme SOLN 2.5MG/2.5ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CF (initial, reauth): 12 months |
| **Other Criteria** | Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations). |

# PYRUKYND (S)

## Products Affected

- Pyrukynd
- Pyrukynd Taper Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of hemolytic anemia confirmed by the presence of chronic hemolysis (e.g., increased indirect bilirubin, elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased reticulocyte count). Diagnosis of pyruvate kinase deficiency confirmed by molecular testing of ALL the following mutations on the PKLR gene: a) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 was a missense variant AND b) Patients is not homozygous for the c.1436G to A (p.R479H) variant AND c) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene. Hemoglobin is less than or equal to 10g/dL. Patient has symptomatic anemia or is transfusion dependent. Exclusion of other causes of hemolytic anemias (e. g., infections, toxins, drugs). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial, Reauth: Prescribed by or in consultation with a hematologist. |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# QINLOCK (S)

**Products Affected**

- Qinlock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gastrointestinal Stromal Tumor (GIST): Diagnosis of gastrointestinal stromal tumor (GIST). Disease is advanced. Patient has received prior treatment with three or more kinase inhibitors (e.g., sunitinib, regorafenib), one of which must include imatinib. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# QUALAQUIN (S)

**Products Affected**

- Quinine Sulfate CAPS 324MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Excluded if used solely for the treatment or prevention of nocturnal leg cramps. |
| **Required Medical Information** | Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 7 days |
| **Other Criteria** | N/A |

# QULIPTA (S)

**Products Affected**

- Qulipta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Episodic Migraine (EM) (initial): Both of the following: 1) Diagnosis of EM and 2) Patient has greater than or equal to 4 migraine days per month. Chronic Migraines (CM) (initial): Diagnosis of CM. Medication overuse headache has been considered and potentially offending medication(s) have been discontinued. Patient has greater than or equal to 8 migraine days per month. All Indications (initial): History of failure (after at least a two month trial), contraindication, or intolerance to two of the following preventive treatments for migraine from different mechanisms of action: a) Elavil (amitriptyline) or Effexor (venlafaxine), OR b) Depakote/Depakote ER (divalproex sodium) or Topamax (topiramate), OR c) Atenolol, propranolol, nadolol, timolol, or metoprolol, OR d) Candesartan, OR e) Lisinopril. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. |
| **Age Restrictions** | EM, CM (initial): 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | EM, CM (init): 6mo. EM, CM (reauth): 12mo. |

| | |
|---|---|
| **Other Criteria** | EM, CM (reauth): Patient has experienced a positive response to therapy (e.g., a reduction in headache frequency and/or intensity, a reduction in the number of workdays missed due to migraines). Use of acute migraine medications [e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., ibuprofen, naproxen), triptans (e.g., eletriptan, rizatriptan, sumatriptan)] has decreased since the start of CGRP therapy. Medication will not be used in combination with another CGRP inhibitor for the preventive treatment of migraines. CM (reauth): Patient continues to be monitored for medication overuse headache. |

# REPATHA (S)

## Products Affected

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | HeFH/ASCVD/Primary HLD (init): One of the following dx: A)HeFH, B)ASCVD, OR C)Primary hyperlipidemia (HLD). One of the following: a) Pt has been receiving the highest tolerable dose of statin therapy, OR b) Patient is statin intolerant as evidenced by an inability to tolerate at least two statins, with at least one started at the lowest starting daily dose, due to intolerable symptoms or clinically significant biomarker changes of liver function or muscle function (e.g., creatine kinase), OR c) Pt has an FDA labeled contraindication to all statins. ONE of the following: 1) One of the following LDL values while on max tolerated lipid lowering tx w/in the last 120 days: a) LDL greater than or equal to 55 mg/dL w/ ASCVD or b) LDL greater than or equal to 70 mg/dL w/o ASCVD. OR 2) Both of the following: a) Patient has been receiving PCSK9 therapy as adjunct to maximally tolerated lipid lowering therapy (e.g., statins, ezetimibe) and b) LDL-C values drawn within the past 12 months while on maximally tolerated lipid lowering therapy is within normal limits. ONE of the following: Pt has been receiving at least 12 weeks of ezetimibe (Zetia) tx as adjunct to max tolerated statin tx OR Pt has a hx of contraindication or intolerance to ezetimibe. HoFH (init): Dx of HoFH as confirmed by one of the following: 1)Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or 2)either untreated/pre-treatment LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. One of the following: 1)Pt is receiving other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). |
| **Age Restrictions** | (Initial) HeFH/HoFH: 10 years or older. |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months |
| **Other Criteria** | HeFH/ASCVD/Primary HLD (reauth): Pt continues to receive other lipid-lowering tx (eg statins, ezetimibe) at max tolerated dose (unless pt has documented inability to take these medications). HoFH (reauth): One of the following: 1)Pt continues to receive other lipid-lowering tx (eg statin, ezetimibe) or 2)Pt has a documented inability to take other lipid-lowering tx (eg statin, ezetimibe). HeFH/ASCVD/Primary HLD/HoFH (reauth): Patient demonstrates positive clinical response to therapy as evidenced by a reduction in LDL-C levels from baseline. |

# RETEVMO (S)

## Products Affected

- Retevmo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Small Cell Lung Cancer: Diagnosis of non-small cell lung cancer (NSCLC). Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medullary Thyroid Cancer (MTC): Diagnosis of medullary thyroid cancer (MTC). Disease is advanced or metastatic. Disease has presence of RET gene mutation tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease requires treatment with systemic therapy. Thyroid Cancer: Diagnosis of thyroid cancer. Disease is advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s) as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Disease requires treatment with systemic therapy. Patient is radioactive iodine-refractory or radioactive iodine therapy is not appropriate. Solid Tumors: Diagnosis of solid tumors. Disease is locally advanced or metastatic. Disease has presence of RET gene fusion-positive tumor(s). ONE of the following: a) Disease has progressed on or following prior systemic treatment (e.g., chemotherapy), OR b) There are no satisfactory alternative treatment options. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Non-Small Cell Lung Cancer, MTC, Thyroid Cancer, Solid Tumors: 12 months |

| | |
|---|---|
| **Other Criteria** | Approve for continuation of prior therapy. |

# REVATIO (S)

## Products Affected

- Sildenafil Citrate TABS 20MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH: Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# REVCOVI (S)

## Products Affected

- Revcovi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of adenosine deaminase deficiency (ADA) with severe combined immunodeficiency (SCID). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# REVLIMID (S)

## Products Affected

- Lenalidomide
- Revlimid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple myeloma (MM): Diagnosis of MM. Myelodysplastic syndromes (MDS): Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion 5q. Mantle cell lymphoma (MCL): Diagnosis of MCL. Follicular Lymphoma (FL): Diagnosis of FL. Marginal Zone Lymphoma (MZL): Diagnosis of MZL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# REZLIDHIA (S)

**Products Affected**

- Rezlidhia

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Presence of a susceptible isocitrate dehydrogenase-1(IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# REZUROCK (S)

## Products Affected

- Rezurock

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic graft versus host disease (cGVHD) (initial): Diagnosis of cGVHD. Trial and failure of two or more lines of systemic therapy (e.g., corticosteroids, mycophenolate, etc.). |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | cGVHD (initial): Prescribed by or in consultation with one of the following: hematologist, oncologist, or physician experienced in the management of transplant patients. |
| **Coverage Duration** | cGVHD (initial, reauth): 12 months |
| **Other Criteria** | cGVHD (reauth): Patient does not show evidence of progressive disease while on therapy. |

# RINVOQ (S)

## Products Affected

- Rinvoq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid arthritis (RA) (init): Diagnosis (Dx) of moderately to severely active RA. RA, PJIA (init): Minimum (min) duration of a 3-mo (RA)/6-wk (PJIA) trial and failure, contraindication, or intolerance (TF/C/I) to 1 of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, (RA only) sulfasalazine. Psoriatic arthritis (PsA) (init): Dx of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (init): Dx of active AS. Non-radiographic axial spondyloarthritis (NRAS, init): Dx of active NRAS. Pt has signs of inflammation. Pt has had an inadequate response or intolerance to 1 TNF inhibitor (eg, certolizumab pegol). AS, NRAS (init): Min duration of a 1-mo TF/C/I to 1 NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PJIA, PsA, AS (init): Pt has had an inadequate response or intolerance to 1 or more TNF inhibitors (eg, adalimumab, etanercept). RA, PJIA, PsA, AS, NRAS (init, reauth): Not used in combo with other JAK inhibitors (JAK-I), biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). Atopic dermatitis (AD) (init): Dx of moderate to severe AD. One of the following: Involvement of at least 10% body surface area (BSA), or SCORing Atopic Dermatitis (SCORAD) index value of at least 25. TF of a min 30-day supply (14-day supply for topical corticosteroids), C/I to 1 of the following: Medium or higher potency topical corticosteroid, Pimecrolimus, Tacrolimus oint, or Eucrisa. One of the following: 1) TF of a min 12-wk supply of at least 1 systemic drug product for the tx of AD (examples include, but are not limited to, Adbry, Dupixent, etc.), OR 2) Pt has a C/I, or tx is inadvisable with both of the following FDA-approved AD therapies: Adbry and Dupixent. Not used in combo with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). |
| **Age Restrictions** | AD (initial): Patient is 12 years of age or older |

| | |
|---|---|
| **Prescriber Restrictions** | RA, PJIA, AS, NRAS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. AD (init): Prescribed by or in consultation with a dermatologist or allergist/immunologist. CD, UC (init): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | RA, PJIA, PsA, AS, NRAS, CD, UC, AD (init): 6 months, (reauth): 12 months. |

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|---|---|
| **Other Criteria** | Polyarticular juvenile idiopathic arthritis (PJIA) (init): Dx of active PJIA. Crohn's disease (CD) (init): Dx of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Ulcerative colitis (UC) (init): Dx of moderately to severely active UC. One of the following: greater than 6 stools/day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (eg, mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). CD, UC (init): Pt has had an inadequate response or intolerance to one or more TNF inhibitors (eg, Humira). Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS, NRAS (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. AD (reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: a) Reduction in BSA involvement from baseline, or b) Reduction in SCORAD index value from baseline. Not used in combination with other JAK-I, biologic immunomodulators, or other immunosuppressants (eg, azathioprine, cyclosporine). CD/UC (Reauth): Pt demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, ESR, CRP]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK-I, biological therapies for CD/UC, or potent immunosuppressants (eg, azathioprine, cyclosporine). |

# RINVOQ LQ (S)

## Products Affected

- Rinvoq Lq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Polyarticular juvenile idiopathic arthritis (PJIA) (init): Diagnosis of active PJIA. Minimum duration of a 6-week trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide. Psoriatic arthritis (PsA) (init): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. PJIA, PsA (init): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). PJIA, PsA (init, reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PJIA (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. |
| **Coverage Duration** | PJIA, PsA (init): 6 months, (reauth): 12 months. |
| **Other Criteria** | PJIA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. |

# ROZLYTREK (S)

## Products Affected

- Rozlytrek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer (NSCLC). Patient has ROS1 rearrangement positive tumor(s). Solid Tumors: Patient has solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion (e.g., ETV6-NTRK3, TPM3-NTRK1, TPR-NTRK1, etc.). Disease is without a known acquired resistance mutation (e.g., TRKA G595R, TRKA G667C or TRKC G623R substitutions). Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: disease has progressed following previous treatment (e.g., surgery, radiation therapy, or systemic therapy) or disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# RUBRACA (S)

**Products Affected**

- Rubraca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Ovarian cancer: Diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. Prostate cancer: Diagnosis of castration-resistant prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# RUXIENCE (S)

## Products Affected

- Ruxience

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-Hodgkin's Lymphoma (NHL): One of the following: 1) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Used as first-line treatment in combination with chemotherapy, 2) Diagnosis of follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. Patient achieved a complete or partial response to a rituximab product in combination with chemotherapy. Used as monotherapy for maintenance therapy, 3) Diagnosis of low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma. One of the following: a) Patient has stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy or, b) Patient achieved a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/ prednisone) chemotherapy, 4) Diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma, 5) Diagnosis of diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma. Used as first-line treatment in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, OR 6) Diagnosis of one of the following previously untreated, advanced stage indications: a) CD-20-positive diffuse large B-cell lymphoma, b) Burkitt lymphoma, c) Burkitt-like lymphoma, or d) mature B-cell acute leukemia. Patient is 6 months of age or older. Used in combination with chemotherapy. Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia. Used in combination with fludarabine and cyclophosphamide. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | NHL, CLL: Prescribed by or in consultation with a hematologist/oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist. |

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| **Coverage Duration** | NHL, CLL: 12 months. WG, MPA: 3 months. RA: 1 month. |
| **Other Criteria** | Rheumatoid Arthritis (RA): Diagnosis of moderately to severely active RA. Used in combination with methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Diagnosis of WG or MPA. Used in combination with glucocorticoids (e.g., prednisone). All uses: Approve for continuation of prior therapy. |

# RYDAPT (S)

**Products Affected**

- Rydapt

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# SABRIL (S)

## Products Affected

- Vigabatrin
- Vigadrone
- Vigpoder

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms. |
| **Age Restrictions** | IS: 1 month to 2 years of age. CPS: 2 years or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# SANDOSTATIN (S)

**Products Affected**

- Octreotide Acetate INJ 1000MCG/ML, 100MCG/ML, 200MCG/ML, 500MCG/ML, 50MCG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly (initial): Diagnosis of acromegaly. One of the following: A) Inadequate response to surgical resection and/or pituitary irradiation OR B) Patient is not a candidate for surgical resection or pituitary irradiation. Trial and failure, contraindication or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses (initial, reauth): 12 months |
| **Other Criteria** | Acromegaly (reauth): Patient demonstrates positive clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): Patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): Patient has improvement in number of diarrhea episodes. |

# SCEMBLIX (S)

**Products Affected**

- Scemblix

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of chronic myelogenous/myeloid leukemia (CML). Disease is Philadelphia chromosome-positive (Ph+). Disease is in chronic phase. One of the following: 1) Patient has been previously treated with two or more alternative tyrosine kinase inhibitors (TKI) [e.g., Bosulif (bosutinib), imatinib, Sprycel (dasatinib), Tasigna (nilotinib), Iclusig (ponatinib)], OR 2) Disease is T315I mutation positive. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# SCIG (S)

## Products Affected

- Cuvitru
- Hizentra INJ 1GM/5ML, 2GM/10ML, 4GM/20ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. Diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) OR one of the following FDA-approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X-linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). |
| **Age Restrictions** | Primary immunodeficiency (Hyqvia only) (initial): Patient is 2 years of age or older. |
| **Prescriber Restrictions** | All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist). |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Subject to Part B vs. Part D review. Patient does not meet criteria for Part B or patient is in a long-term care facility. All uses (reauth): Patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy. |

# SIGNIFOR (S)

**Products Affected**

- Signifor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cushing's disease (initial): Diagnosis of Cushing's disease. One of the following: a) Pituitary surgery has not been curative for the patient or b) Patient is not a candidate for pituitary surgery. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Cushing's disease (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Cushing's disease (initial, reauth): 12 months |
| **Other Criteria** | Cushing's disease (reauth): Patient demonstrates positive clinical response to therapy (e.g., a clinically meaningful reduction in 24-hour urinary free cortisol levels, improvement in signs or symptoms of the disease). |

# SKYCLARYS (S)

**Products Affected**

- Skyclarys

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of Friedreich's ataxia confirmed via genetic testing demonstrating mutation in the FXN gene. Patient has a Modified Friedreich's Ataxia Rating Scale (mFARS) score of greater than or equal to 20 and less than or equal to 80. Patient has a B-type natriuretic peptide value less than or equal to 200 pg/mL. |
| **Age Restrictions** | Initial: Patient is 16 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: Neurologist, Neurogeneticist, or Physiatrist (Physical Medicine and Rehabilitation Specialist). |
| **Coverage Duration** | Initial, Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# SKYRIZI (S)

## Products Affected

- Skyrizi INJ 150MG/ML, 180MG/1.2ML, 360MG/2.4ML, 75MG/0.83ML
- Skyrizi Pen

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active CD. Will be used as a maintenance dose following the intravenous induction doses. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction doses. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All uses (initial): 6 months, (reauth): 12 months |

| | |
|---|---|
| **Other Criteria** | Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. CD, UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

# SKYRIZI IV (S)

## Products Affected

- Skyrizi INJ 600MG/10ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Crohn's disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Will be administered as an intravenous induction dose. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | 3 months |
| **Other Criteria** | N/A |

# SOMATULINE DEPOT (S)

## Products Affected

- Somatuline Depot

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly: Diagnosis of acromegaly. One of the following: A) Inadequate response to one of the following: surgery or radiotherapy, OR B) Not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) (120mg/0.5mL strength only): Diagnosis of GEP-NETs. Disease is one of the following: (a) unresectable, locally advanced or (b) metastatic. Carcinoid syndrome (120mg/0.5mL strength only): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. GEP-NETs (initial): Prescribed by or in consultation with an oncologist. Carcinoid syndrome (initial): Prescribed by or in consultation with an endocrinologist or oncologist. |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# SOMAVERT (S)

## Products Affected

- Somavert

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acromegaly (initial): Diagnosis of acromegaly. One of the following: 1) failure to one of the following: surgery, radiation therapy, or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) or 2) not a candidate for one of the following: surgery, radiation therapy, or dopamine agonist (e.g., bromocriptine, cabergoline) therapy. One of the following: 1) inadequate response, contraindication, or intolerance to a somatostatin analog (e.g., octreotide, lanreotide) or 2) clinical rationale provided for preferred treatment with pegvisomant (e.g., comorbid diabetes mellitus is present with acromegaly). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Acromegaly (initial): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | Initial and reauth: 12 months |
| **Other Criteria** | Acromegaly (reauth): Patient has experienced a positive clinical response to therapy (biochemical control, decrease or normalization of IGF-1 levels). |

# SOTYKTU (S)

**Products Affected**

- Sotyktu

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (initial): Diagnosis of moderate-to-severe plaque psoriasis. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Not used in combination with other potent immunosuppressants (eg, azathioprine, cyclosporine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | Plaque psoriasis (initial): 6 months. Plaque psoriasis (reauth): 12 months. |
| **Other Criteria** | Plaque psoriasis (reauth): Patient demonstrates positive clinical response to therapy. Not used in combination with other potent immunosuppressants (eg, azathioprine, cyclosporine, biologic DMARDs). |

# SPEVIGO (S)

## Products Affected

- Spevigo INJ 150MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of generalized pustular psoriasis (GPP) as defined by the following: Primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques). Subcutaneous formulation will not be used to treat GPP flare. Patient weighs at least 40kg. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a dermatologist. |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# SPRAVATO (S)

## Products Affected

- Spravato 56mg Dose
- Spravato 84mg Dose

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: A) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has not experienced a clinical meaningful improvement after treatment with at least two antidepressants from different classes for an adequate duration (at least 4 weeks each) in the current depressive episode OR B) Both of the following: 1) Diagnosis of major depressive disorder and 2) Patient has both of the following: a) depressive symptoms and b) acute suicidal ideation or behavior. Used in combination with an oral antidepressant (e.g., duloxetine, escitalopram, sertraline). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a psychiatrist |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# SPRYCEL (S)

**Products Affected**

- Sprycel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Philadelphia chromosome positive (Ph+)/BCR ABL chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML. Ph+/BCR ABL acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL ALL. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All Uses: 12 months |
| **Other Criteria** | All Uses: Approve for continuation of prior therapy. |

# STELARA (IV) (S)

**Products Affected**

- Stelara INJ 130MG/26ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Crohn's Disease (CD): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, azathioprine, methotrexate, corticosteroid (eg, prednisone). Ulcerative Colitis (UC): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), or an aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | One time |
| **Other Criteria** | Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease/ulcerative colitis: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg. |

# STELARA (S)

**Products Affected**

- Stelara INJ 45MG/0.5ML, 90MG/ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Plaque psoriasis (Initial - 45mg/0.5mL): Diagnosis of moderate to severe plaque psoriasis. Plaque psoriasis (Initial - 90mg/1mL): Diagnosis of moderate to severe plaque psoriasis. Patient's weight is greater than 100 kg (220 lbs). Plaque psoriasis (Initial): One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Psoriatic arthritis (PsA) (Initial - 45mg/0.5mL): Diagnosis of active PsA. PsA (Initial - 90mg/1mL): Diagnosis of active PsA. Patient's weight is greater than 100 kg (220 lbs). Diagnosis of co-existent moderate to severe psoriasis. PsA (Initial): One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Crohn's disease (CD) (Initial): Diagnosis of moderately to severely active Crohn's disease. Will be used as a maintenance dose following the intravenous induction dose. |
| **Age Restrictions** | Plaque psoriasis, PsA: Patient is 6 years of age or older. |
| **Prescriber Restrictions** | Plaque psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. CD and UC (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | All uses (Initial): 6 months. All uses (reauth): 12 months |

| | |
|---|---|
| **Other Criteria** | Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Will be used as a maintenance dose following the intravenous induction dose. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. Plaque psoriasis (Reauth): Patient demonstrates positive clinical response to therapy. CD (Reauth), UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

# STIVARGA (S)

**Products Affected**

- Stivarga

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Metastatic colorectal cancer (mCRC): Diagnosis of mCRC. Gastrointestinal stromal tumor (GIST): Diagnosis of locally advanced, unresectable or metastatic GIST. Hepatocellular Carcinoma (HCC): Diagnosis of HCC. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# STRENSIQ (S)

**Products Affected**

- Strensiq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hypophosphatasia (initial): Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia. One of the following: 1) Both of the following: a) Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range AND b) Patient has an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]) OR 2) Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing. For patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Hypophosphatasia (initial, reauth): Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist |
| **Coverage Duration** | Hypophosphatasia (initial): 6 months, (reauth): 12 months |
| **Other Criteria** | Hypophosphatasia (reauth): Patient demonstrates positive response to therapy. For patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg. |

# SUCRAID (S)

**Products Affected**

- Sucraid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Congenital Sucrase-Isomaltase Deficiency (CSID) (initial): Diagnosis of sucrase deficiency (which is part of congenital sucrose-isomaltase deficiency [CSID]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CSID (initial): Prescribed by or in consultation with a gastroenterologist or geneticist. |
| **Coverage Duration** | CSID (initial, reauth): 12 months. |
| **Other Criteria** | CSID (reauth): Patient demonstrates positive clinical response to therapy. |

# SUTENT (S)

## Products Affected

- Sunitinib Malate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on, or contraindication or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# SYPRINE (S)

## Products Affected

- Clovique
- Trientine Hydrochloride CAPS 250MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of Wilson's disease (i.e., hepatolenticular degeneration). Trial and failure, contraindication, or intolerance to a penicillamine product (e.g., Depen, Cuprimine) |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy |

# TABRECTA (S)

**Products Affected**

- Tabrecta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of non-small cell lung cancer (NSCLC). Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping positive tumors as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TAFAMIDIS (S)

## Products Affected

- Vyndamax
- Vyndaqel

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM) (initial): Diagnosis of transthyretin-mediated amyloidosis with cardiomyopathy (ATTR-CM). One of the following: 1) Patient has a transthyretin (TTR) mutation (e.g., V122I), 2) Cardiac or noncardiac tissue biopsy demonstrating histologic confirmation of TTR amyloid deposits, OR 3) All of the following: i) echocardiogram or cardiac magnetic resonance imaging suggestive of amyloidosis, ii) scintigraphy scan suggestive of cardiac TTR amyloidosis, and iii) absence of light-chain amyloidosis. One of the following: 1) History of heart failure (HF), with at least one prior hospitalization for HF, OR 2) Presence of clinical signs and symptoms of HF (e.g., dyspnea, edema). Patient has New York Heart Association (NYHA) Functional Class I, II, or III heart failure. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | ATTR-CM (initial, reauth): Prescribed by or in consultation with a cardiologist |
| **Coverage Duration** | ATTR-CM (initial, reauth): 12 months |
| **Other Criteria** | ATTR-CM (reauth): Patient demonstrates positive clinical response to therapy. Patient continues to have New York Heart Association (NYHA) Functional Class I, II, or III heart failure. |

# TAFINLAR (S)

## Products Affected

- Tafinlar

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable or metastatic melanoma AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) OR both of the following: cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and medication is used in combination with Mekinist (trametinib). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): Diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib) . |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. Solid tumors: Diagnosis of solid tumors. Disease is unresectable or metastatic. Patient has progressed on or following prior treatment and have no satisfactory alternative treatment options. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib). Low-grade Glioma: Diagnosis of low-grade glioma. Patient requires systemic therapy. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Medication is used in combination with Mekinist (trametinib). |

# TAGRISSO (S)

## Products Affected

- Tagrisso

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): One of the following: A) All of the following: Diagnosis of metastatic NSCLC. One of the following: 1) Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA), OR 2) Both of the following: a) Patient has known active EGFR T790M mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) and b) Patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), or Vizimpro (dacomitinib). OR B) All of the following: Diagnosis of NSCLC. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: 1) Patient is receiving as adjuvant therapy, and 2) Patient has had a complete surgical resection of the primary NSCLC tumor. OR C) All of the following: Diagnosis of NSCLC. Disease is locally advanced. Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations as detected by an U.S. FDA-approved test or a test performed at a facility approved by CLIA. Used in combination with both of the following: a) Pemetrexed, and b) Platinum-based chemotherapy (e.g., cisplatin, carboplatin). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |

| | |
|---|---|
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TALZENNA (S)

**Products Affected**

- Talzenna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. Prostate cancer: Diagnosis of metastatic castration-resistant prostate cancer (mCRPC). Disease is homologous recombination repair (HRR) gene-mutated. Taken in combination with Xtandi (enzalutamide). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TARCEVA (S)

**Products Affected**

- Erlotinib Hydrochloride TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND erlotinib will be used in combination with gemcitabine. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# TARGRETIN (S)

**Products Affected**

- Bexarotene

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, brentuximab vedotin, methotrexate]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TASIGNA (S)

**Products Affected**

- Tasigna

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL CML |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TAZVERIK (S)

**Products Affected**

- Tazverik

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epithelioid sarcoma: Diagnosis of epithelioid sarcoma. Disease is one of the following: metastatic or locally advanced. Patient is not eligible for complete resection. Follicular lymphoma: Diagnosis of follicular lymphoma. Disease is one of the following: relapsed or refractory. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TECFIDERA (S)

## Products Affected

- Dimethyl Fumarate CPDR
- Dimethyl Fumarate Starterpack CDPK 0

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Multiple Sclerosis (MS) (initial, reauth): Not used in combination with another disease-modifying therapy for MS. |
| **Required Medical Information** | MS (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (initial, reauth): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | MS (initial, reauth): 12 months |
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). |

# TEGSEDI (S)

**Products Affected**

- Tegsedi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) (initial): Diagnosis of hATTR amyloidosis with polyneuropathy. Patient has a transthyretin (TTR) mutation (e.g., V30M). One of the following: 1) Patient has a baseline polyneuropathy disability (PND) score less than or equal to IIIb, 2) Patient has baseline familial amyloidotic polyneuropathy (FAP) stage of 1 or 2, OR 3) Patient has a baseline neuropathy impairment score (NIS) between 10 and 130. Presence of clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | hATTR amyloidosis (initial): Prescribed by or in consultation with a neurologist |
| **Coverage Duration** | hATTR amyloidosis (initial, reauth): 12 months |
| **Other Criteria** | hATTR amyloidosis (reauth): Patient demonstrates postive clinical response to therapy. |

# TEPMETKO (S)

**Products Affected**

- Tepmetko

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Presence of mesenchymal-epithelial transition (MET) exon 14 skipping alterations. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TERIPARATIDE (S)

## Products Affected

- Forteo INJ 600MCG/2.4ML
- Teriparatide

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Postmenopausal osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia (initial): Diagnosis of one of the following: a) postmenopausal osteoporosis or osteopenia or b) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) Both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) Both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Glucocorticoid-Induced Osteoporosis: See Other Criteria section. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses (initial): 24 months. All uses (reauth): 12 months. |

| | |
|---|---|
| **Other Criteria** | Glucocorticoid-Induced Osteoporosis (initial): Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: 1) BMD T-score less than or equal to -2.5 based on BMD measurements from lumbar spine, femoral neck, total hip, or radius (one-third radius site), or 2) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions, 3) History of one of the following fractures resulting from minimal trauma: vertebral compression fx, fx of the hip, fx of the distal radius, fx of the pelvis, or fx of the proximal humerus, or 4) One of the following: a) glucocorticoid dosing of at least 30 mg per day, or b) cumulative glucocorticoid dosing of at least 5 grams per year. TF/C/I to one bisphosphonate (e.g., alendronate). All uses (initial, reauth): One of the following: 1) Treatment duration of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime, or 2) Patient remains at or has returned to having a high risk for fracture despite a total of 24 months of use of parathyroid hormones [e.g., teriparatide, Tymlos (abaloparatide)]. |

# TESTOSTERONE (S)

## Products Affected

- Testosterone GEL 25MG/2.5GM, 50MG/5GM
- Testosterone Cypionate INJ 100MG/ML, 200MG/ML
- Testosterone Pump

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. Using hormones to change characteristics to align with gender expression. |
| **Age Restrictions** | Testosterone cypionate only: HG (init): 12 years of age or older. All other testosterone: HG (init): Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GD: 12 mo. |

| | |
|---|---|
| **Other Criteria** | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |

# TESTOSTERONE ENANTHATE (S)

**Products Affected**

- Testosterone Enanthate INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than 300 ng/dL (10.4 nmol/L) or less than the reference range for the lab, OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome), OR 4) Both of the following: a) Patient is continuing testosterone therapy, and b) One of the following: i) Follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is within or below the normal limits of the reporting lab, or ii) follow-up total serum T level or calculated free or bioavailable T level drawn within the past 12 months is outside of upper limits of normal for the reporting lab and the dose is adjusted. Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Dysphoria (GD)/Gender Incongruence (off-label): Dx of GD/Gender Incongruence. Using hormones to change characteristics to align with gender expression. |
| **Age Restrictions** | HG (init): Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GD: 12 mo. DP: 6 mo. |

| | |
|---|---|
| **Other Criteria** | HG (Reauth): 1) Follow-up total serum T level within or below the normal limits of the reporting lab, or 2) Follow-up total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Follow-up calculated free or bioavailable T level within or below the normal limits of the reporting lab, or follow-up calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted. |

# THALOMID (S)

**Products Affected**

- Thalomid

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TIBSOVO (S)

## Products Affected

- Tibsovo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Relapsed or refractory Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Newly-Diagnosed AML: Diagnosis of newly-diagnosed AML. One of the following: 1) patient is greater than or equal to 75 years old OR 2) patient has comorbidities that preclude use of intensive induction chemotherapy. Locally Advanced or Metastatic Cholangiocarcinoma: Diagnosis of cholangiocarcinoma. Disease is locally advanced or metastatic. Patient has been previously treated. Relapsed or Refractory Myelodysplastic Syndromes: Diagnosis of myelodysplastic syndromes (MDS). Disease is relapsed or refractory. All indications: Patient has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., Abbott RealTime IDH1 assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TOPICAL RETINOID (S)

**Products Affected**

- Tretinoin CREA 0.025%, 0.05%

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acne vulgaris: Diagnosis of acne vulgaris (i.e., acne). |
| **Age Restrictions** | PA applies to members 26 years of age or older |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# TORPENZ (S)

**Products Affected**

- Torpenz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention. Renal cell carcinoma: Diagnosis of advanced renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib). Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC. Breast Cancer: Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, non-functional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease. |
| **Age Restrictions** | SEGA associated with TSC: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | All uses: 12 months |
| **Other Criteria** | All Indications: Approve for continuation of prior therapy. |

# TRACLEER (S)

## Products Affected

- Bosentan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH (Initial): 6 months. PAH (Reauth): 12 months |
| **Other Criteria** | PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# TRAZIMERA (S)

## Products Affected

- Trazimera

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Platinol (cisplatin) and Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TRELSTAR (S)

**Products Affected**

- Trelstar Mixject INJ 11.25MG, 22.5MG

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to any brand Lupron formulation. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TRIPTODUR (S)

**Products Affected**

- Triptodur

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range. Trial and failure or intolerance to Lupron Depot-Ped. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CPP (initial, reauth): Prescribed by or in consultation with an endocrinologist. |
| **Coverage Duration** | CPP (initial, reauth): 12 months |
| **Other Criteria** | CPP (reauth): Patient demonstrates positive clinical response to therapy. |

# TRUQAP (S)

**Products Affected**

- Truqap

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of breast cancer. Disease is one of the following: locally advanced or metastatic. Will be taken in combination with fulvestrant. Disease is hormone receptor (HR)-positive. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has one or more PIK3CA/AKT1/PTEN-alterations as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). One of the following: A) Following progression on at least one endocrine-based regimen in the metastatic setting (e.g., anastrozole, letrozole, exemestane, tamoxifen, etc.) OR B) Recurrence on or within 12 months of completing adjuvant therapy (e.g., chemotherapy). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TRUSELTIQ (S)

**Products Affected**

- Truseltiq

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of cholangiocarcinoma. Disease is one of the following: a) unresectable locally advanced or b) metastatic. Disease has presence of a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has been previously treated. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TUKYSA (S)

**Products Affected**

- Tukysa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast cancer: Diagnosis of breast cancer. Disease is one of the following: a) advanced unresectable or b) metastatic. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Used in combination with trastuzumab and capecitabine. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TURALIO (S)

**Products Affected**

- Turalio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Tenosynovial Giant Cell Tumor (TGCT): Diagnosis of TGCT. Patient is symptomatic. Patient is not a candidate for surgery due to worsening functional limitation or severe morbidity with surgical removal. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TYKERB (S)

## Products Affected

- Lapatinib Ditosylate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Trastuzumab, Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrozole)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# TYMLOS (S)

**Products Affected**

- Tymlos

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following diagnoses: 1) postmenopausal osteoporosis or osteopenia, OR 2) primary or hypogonadal osteoporosis or osteopenia. One of the following: Set I) For diagnosis of osteoporosis, both of the following: A) Bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) trial and failure, contraindication, or intolerance (TF/C/I) to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]), or Set II) For diagnosis of osteopenia, both of the following: A) BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) One of the following: 1) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) TF/C/I to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and ii) one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: a) major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) hip fracture at 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (e.g., teriparatide, Tymlos [abaloparatide]) has not exceeded a total of 24 months during the patient's lifetime. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 24 months (max 24 months of therapy per lifetime) |

| | |
|---|---|
| **Other Criteria** | N/A |

# TYSABRI (S)

**Products Affected**

- Tysabri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Sclerosis (MS) (initial): Diagnosis of a relapsing form of MS (eg, clinically isolated syndrome, relapsing-remitting disease, secondary progressive disease, including active disease with new brain lesions). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one disease-modifying therapy for MS (e.g., Gilenya [fingolimod], Avonex [Interferon beta-1a], Betaseron [Interferon beta-1b]), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) for continuation of prior therapy. MS (init, reauth): Not used in combination with another disease-modifying therapy for MS. Crohn's Disease (CD) (initial): Diagnosis of moderately to severely active CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). TF/C/I to one of the following conventional therapies: corticosteroids (eg, prednisone), 6-mercaptopurine, azathioprine, methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). TF/C/I to a TNF-inhibitor (eg, adalimumab). CD (initial and reauth): Not used in combination with TNF inhibitors (e.g., adalimumab) or immunosuppressants (eg, 6-MP, azathioprine, cyclosporine, or methotrexate). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | MS (init, reauth): Prescribed by or in consultation with a neurologist. CD (initial): Prescribed by or in consultation with a gastroenterologist. |
| **Coverage Duration** | MS (init, reauth): 12mo. CD (Init): 3 mo. CD (Reauth): 12 mo. |

| | |
|---|---|
| **Other Criteria** | MS (reauth): Patient demonstrates positive clinical response to therapy (e.g., stability in radiologic disease activity, clinical relapses, disease progression). CD (reauth): Patient demonstrates positive clinical response (eg, improved disease activity index) to therapy. |

# UBRELVY (S)

**Products Affected**

- Ubrelvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of migraine with or without aura. Will be used for the acute treatment of migraine. Trial and failure or intolerance to one triptan (e.g., eletriptan, rizatriptan, sumatriptan) or a contraindication to all triptans. Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines. |
| **Age Restrictions** | Initial: 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial: 3 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient has experienced a positive response to therapy (e.g., reduction in pain, photophobia, phonophobia, nausea). Will not be used for preventive treatment of migraine. Medication will not be used in combination with another oral CGRP inhibitor for the acute treatment of migraines. |

# UDENYCA (S)

**Products Affected**

- Udenyca

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. Acute radiation syndrome (ARS) (off-label): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses: Prescribed by or in consultation with a hematologist/oncologist |
| **Coverage Duration** | ARS: 1 mo. FN (prophylaxis, treatment): 3 mo or duration of tx. |
| **Other Criteria** | N/A |

# UDENYCA ONBODY (S)

**Products Affected**

- Udenyca Onbody

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Febrile neutropenia (FN) prophylaxis: Patient will be receiving prophylaxis for FN due to one of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown, 3) patient is receiving chemotherapy regimen(s) associated with greater than 20% incidence of FN, 4) both of the following: a) patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN, AND b) patient has one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia, OR 5) Both of the following: a) patient is receiving myelosuppressive anticancer drugs associated with neutropenia, AND b) patient has a history of FN or dose-limiting event during a previous course of chemotherapy (secondary prophylaxis). Treatment of FN (off-label): Patient has received or is receiving myelosuppressive anticancer drugs associated with neutropenia. Diagnosis of FN. Patient is at high risk for infection-associated complications. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses: Prescribed by or in consultation with a hematologist/oncologist |
| **Coverage Duration** | FN (prophylaxis, treatment): 3 mo or duration of tx. |
| **Other Criteria** | N/A |

# VALCHLOR (S)

**Products Affected**

- Valchlor

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy (e.g., topical corticosteroids [e.g., clobetasol, fluocinonide], bexarotene topical gel [Targretin topical gel], etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VANFLYTA (S)

**Products Affected**

- Vanflyta

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Acute Myeloid Leukemia (AML): Diagnosis of AML. Patient has a FMS-like tyrosine kinase 3 (FLT3) internal tandem duplication (FLT3-ITD) mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Both of the following: a) Used in combination with standard cytarabine and anthracycline (e.g., daunorubicin, idarubicin) induction and cytarabine consolidation, and b) Used as maintenance monotherapy following consolidation chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VARIZIG (S)

**Products Affected**

- Varizig INJ 125UNIT/1.2ML

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). |
| **Required Medical Information** | Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 3 months (approve one dose only) |
| **Other Criteria** | N/A |

# VENCLEXTA (S)

## Products Affected

- Venclexta
- Venclexta Starting Pack

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Acute Myeloid Leukemia (AML): Diagnosis of newly diagnosed AML. Used in combination with azacitidine, or decitabine, or low-dose cytarabine. One of the following: 1) age 75 years or older OR 2) comorbidities that preclude use of intensive induction chemotherapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VENTAVIS (S)

## Products Affected

- Ventavis

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist. |
| **Coverage Duration** | PAH (Initial): 6 months. (Reauth): 12 months |
| **Other Criteria** | Subject to Part B vs D review. PAH (Reauth): Patient demonstrates positive clinical response to therapy. |

# VEOPOZ (S)

**Products Affected**

- Veopoz

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of active CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. Patient has a confirmed genotype of biallelic CD55 loss-of-function mutation. Patient has hypoalbuminemia (serum albumin concentration of less than or equal to 3.2 g/dL). Patient has at least one of the following signs or symptoms within the last six months: abdominal pain, diarrhea, peripheral edema, or facial edema. |
| **Age Restrictions** | Initial: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an immunologist, geneticist, hematologist, or gastroenterologist. |
| **Coverage Duration** | Initial, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# VERQUVO (S)

## Products Affected

- Verquvo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic Heart Failure (CHF) (initial): Diagnosis of CHF. Patient has an ejection fraction less than 45 percent. Patient has New York Heart Association (NYHA) Class II, III, or IV symptoms. One of the following: A) Patient was hospitalized for heart failure within the last 6 months, or B) Patient used outpatient intravenous diuretics (e.g., bumetanide, furosemide) for heart failure within the last 3 months. Trial and failure, contraindication, or intolerance to two of the following at a maximally tolerated dose: A) One of the following: 1) Angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril), 2) Angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan), or 3) Angiotensin receptor-neprilysin inhibitor (ARNI) [e.g., Entresto (sacubitril and valsartan)], B) One of the following: 1) bisoprolol, 2) carvedilol, or 3) metoprolol succinate extended release, C) Sodium-glucose co-transporter 2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin), Farxiga (dapagliflozin), Xigduo XR (dapagliflozin and metformin)], or D) Mineralocorticoid receptor antagonist (MRA) [e.g., eplerenone, spironolactone]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | CHF (initial): Prescribed by or in consultation with a cardiologist. |
| **Coverage Duration** | CHF (initial, reauth): 12 months |
| **Other Criteria** | CHF (reauth): Patient demonstrates positive clinical response to therapy. |

# VERZENIO (S)

**Products Affected**

- Verzenio

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Breast Cancer: Diagnosis of breast cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VIMIZIM (S)

## Products Affected

- Vimizim

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Mucopolysaccharidosis (initial): Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome) confirmed by both of the following: a) documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.) and b) documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Initial, reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# VITRAKVI (S)

## Products Affected

- Vitrakvi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Presence of solid tumors (e.g., salivary gland, soft tissue sarcoma, infantile fibrosarcoma, thyroid cancer, lung, melanoma, colon, etc.). Disease is positive for neurotrophic receptor tyrosine kinase (NTRK) gene fusion (e.g. ETV6-NTRK3, TPM3-NTRK1, LMNA-NTRK1, etc.). Disease is without a known acquired resistance mutation [e.g., TRKA G595R substitution, TRKA G667C substitution, or other recurrent kinase domain (solvent front and xDFG) mutations]. Disease is one of the following: metastatic or unresectable (including cases where surgical resection is likely to result in severe morbidity). One of the following: Disease has progressed on previous treatment (e.g., surgery, radiotherapy, or systemic therapy) OR Disease has no satisfactory alternative treatments. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VIZIMPRO (S)

## Products Affected

- Vizimpro

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. Disease is metastatic. Disease is positive for one of the following epidermal growth factor receptor (EGFR) mutations: exon 19 deletion or exon 21 L858R substitution. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VONJO (S)

**Products Affected**

- Vonjo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of ONE of the following: a) Primary myelofibrosis, b) Post-polycythemia vera myelofibrosis, OR c) Post-essential thrombocythemia myelofibrosis. Disease is intermediate or high risk. Pre-treatment platelet count below 50 x 10^9/L. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VORICONAZOLE INJECTION (S)

## Products Affected

- Voriconazole INJ

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Invasive aspergillosis: Diagnosis of invasive aspergillosis (IA). Candidemia: Diagnosis of candidemia. One of the following: (1) patient is non-neutropenic or (2) infection is located in skin, abdomen, kidney, bladder wall, or wounds. Esophageal Candidiasis: Diagnosis of esophageal candidiasis. Mycosis: Diagnosis of fungal infection caused by Scedosporium apiospermum (asexual form of Pseudallescheria boydii) or Fusarium spp. including Fusarium solani. For fusariosis: Patient is intolerant of, or refractory to, other therapy (e.g., liposomal amphotericin B, amphotericin B lipid complex). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 weeks |
| **Other Criteria** | N/A |

# VOSEVI (S)

## Products Affected

- Vosevi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and not used in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine. |
| **Coverage Duration** | 12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline. |
| **Other Criteria** | N/A |

# VOTRIENT (S)

## Products Affected

- Pazopanib Hydrochloride
- Votrient

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# VOWST (S)

**Products Affected**

- Vowst

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of recurrent clostridioides difficile infection (CDI) as defined by both of the following: 1) Presence of diarrhea defined as a passage of 3 or more loose bowel movements within a 24-hour period for two consecutive days, and 2) A positive stool test for C.difficile toxin or toxigenic C.difficile. Patient has a history of two or more recurrent episodes of CDI within 12 months. All of the following: 1) Patient has completed at least 10 consecutive days of one of the following antibiotic therapies 2-4 days prior to initiating Vowst: oral vancomycin or Dificid (fidaxomicin), 2) Patient has completed the recommended course of magnesium citrate the day before and at least 8 hours prior to initiating Vowst, and 3) Previous episode of CDI is under control (e.g., less than 3 unformed/loose [i.e., Bristol Stool Scale type 6-7] stools/day for 2 consecutive days). |
| **Age Restrictions** | Patient is 18 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a gastroenterologist or infectious disease specialist. |
| **Coverage Duration** | 14 days |
| **Other Criteria** | N/A |

# VYJUVEK (S)

**Products Affected**

- Vyjuvek

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of dystrophic epidermolysis bullosa (DEB). Patient has mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Medication is being used for the treatment of wounds. Medication will be applied by a healthcare professional. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated. |
| **Age Restrictions** | Initial: Patient is 6 months of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with a dermatologist OR specialist with expertise in wound care. |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months. |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. Wound(s) being treated meet all of the following criteria: a) adequate granulation tissue, b) excellent vascularization, c) no evidence of active wound infection in the wound being treated, and d) no evidence or history of squamous cell carcinoma in the wound being treated. |

# WELIREG (S)

**Products Affected**

- Welireg

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | von Hippel-Lindau (VHL) disease: Diagnosis of VHL disease. Patient requires therapy for one of the following: a) renal cell carcinoma (RCC), b) central nervous system (CNS) hemangioblastoma, or c) pancreatic neuroendocrine tumor (pNET). Patient does not require immediate surgery. Advanced Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma. Disease has progressed after treatment with both of the following: a) One of the following: i) Programmed death receptor-1 (PD-1) inhibitor [e.g., Keytruda (pembrolizumab), Opdivo (nivolumab)], or ii) Programmed death-ligand 1 (PD-L1) inhibitor [e.g., Bavencio (avelumab), Imfinzi (durvalumab)], and b) Vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) [e.g., Votrient (pazopanib), Inlyta (axitinib)]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XALKORI (S)

**Products Affected**

- Xalkori

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of advanced or metastatic NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) or B) Patient has MET amplification- or ROS1 rearrangement-positive tumor as detected with an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Anaplastic Large Cell Lymphoma (ALCL): Diagnosis of systemic ALCL. Disease is relapsed or refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Inflammatory Myofibroblastic Tumor (IMT): Diagnosis of IMT. Disease is one of the following: a) unresectable, b) recurrent, or c) refractory. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | IMT, ALCL: Patient is 1 year of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XCOPRI (S)

**Products Affected**

- Xcopri

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of partial onset seizures. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XELJANZ (S)

## Products Affected

- Xeljanz
- Xeljanz Xr

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Xeljanz tab/Xeljanz XR tab: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Ankylosing spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one nonsteroidal anti-inflammatory drug (NSAID) (eg, ibuprofen, naproxen) at maximally tolerated doses. RA, PsA, AS (Initial): Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, aminosalicylate (e.g., mesalamine, olsalazine, sulfasalazine), azathioprine, or corticosteroids (eg, prednisone). Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab). Not used in combination with other Janus kinase (JAK) inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | RA, PJIA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist. |

| | |
|---|---|
| **Coverage Duration** | RA/PJIA/PsA/AS (initial): 6 mo, (reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo. |
| **Other Criteria** | Xeljanz: Polyarticular course juvenile idiopathic arthritis (PJIA) (Initial): Diagnosis of active polyarticular course juvenile idiopathic arthritis. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Patient has had an inadequate response or intolerance to one or more TNF inhibitors (eg, adalimumab, etanercept). RA, PsA, AS, PJIA (Initial): Not used in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or potent immunosuppressants (eg, azathioprine, cyclosporine). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. RA, PsA, AS, PJIA (reauth): Not used in combination with other JAK inhibitors, biologic DMARDs, or potent immunosuppressants (eg, azathioprine, cyclosporine). UC (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline OR reversal of high fecal output state. Not used in combination with other JAK inhibitors, biological therapies for UC, or potent immunosuppressants (e.g., azathioprine, cyclosporine). |

# XENAZINE (S)

## Products Affected

- Tetrabenazine

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Diagnosis of tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication, OR 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Trial and failure, contraindication, or intolerance to Haldol (haloperidol). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist. |
| **Coverage Duration** | All uses: (initial) 3 months. (Reauth) 12 months. |
| **Other Criteria** | All indications (Reauth): Patient demonstrates positive clinical response to therapy. |

# XERMELO (S)

**Products Affected**

- Xermelo

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist |
| **Coverage Duration** | Initial: 6 months. Reauth: 12 months |
| **Other Criteria** | Carcinoid syndrome diarrhea (Reauthorization): Patient demonstrates positive clinical response to therapy AND drug will continue to be used in combination with SSA therapy. |

# XGEVA (S)

**Products Affected**

- Xgeva

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Both of the following: a) Diagnosis of multiple myeloma and b) Trial and failure, contraindication (e.g., renal insufficiency), or intolerance to one bisphosphonate therapy, OR 2) Both of the following: a) Diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer) and b) Documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) Diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) Diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one bisphosphonate therapy. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | MM/BMST, GCTB: 12 mo. HCM: 2 mo. |
| **Other Criteria** | GCTB: Approve for continuation of prior therapy. |

# XIFAXAN (S)

**Products Affected**

- Xifaxan

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Travelers' diarrhea (TD): Diagnosis of travelers' diarrhea. One of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis (ppx) of hepatic encephalopathy (HE) recurrence (initial): Used for the prophylaxis of hepatic encephalopathy recurrence, AND One of the following: 1) Trial and failure, contraindication or intolerance to lactulose or 2) Add-on treatment to lactulose. Treatment (tx) of HE: Used for the treatment of HE. One of the following: 1) Trial and failure, contraindication, or intolerance to lactulose or 2) Add-on treatment to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide]. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | TD: 14 days. HE (tx): 12 months. HE (ppx) (init, reauth): 12 months. IBS-D (init, reauth): 2 weeks. |
| **Other Criteria** | Prophylaxis of HE recurrence (reauth): Patient demonstrates positive clinical response to therapy. IBS-D (reauth): Symptoms of IBS continue to persist. Patient demonstrates positive clinical response to therapy. |

# XOLAIR (S)

## Products Affected

- Xolair

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. One of the following: A) All of the following: a) Patient is 6 years of age or older but less than 12 years of age, b) Pretreatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL, c) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Both of the following: 1) Medium-dose inhaled corticosteroid [ICS] (eg, greater than 100-200 mcg fluticasone propionate equivalent/day), and 2) Additional asthma controller medication (eg, leukotriene receptor antagonist [LTRA] [eg, montelukast], long-acting beta-2 agonist [LABA] [eg, salmeterol], long-acting muscarinic antagonist [LAMA] [eg, tiotropium]), OR ii) One medium dosed combination ICS/LABA product (eg, Advair Diskus [fluticasone propionate 100mcg/salmeterol 50mcg], Symbicort [budesonide 80mcg/formoterol 4.5mcg], Breo Ellipta [fluticasone furoate 50 mcg/vilanterol 25 mcg]), OR B) All of the following: a) Patient is 12 years of age or older, b) Treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL, c) Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: i) Both of the following: 1) High-dose ICS [eg, greater than 500 mcg fluticasone propionate equivalent/day], and 2) Additional asthma controller medication (eg, LTRA [eg, montelukast], LABA [eg, salmeterol], LAMA [eg, tiotropium]), OR ii) One maximally-dosed combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone/vilanterol)]. |
| **Age Restrictions** | IgE-Mediated Food Allergy (init): Patient is 1 year of age or older. |

| | |
|---|---|
| **Prescriber Restrictions** | Asthma (init/reauth): Prescribed by or in consultation with an allergist/immunologist, or pulmonologist. CSU (init): Prescribed by or in consultation with an allergist/immunologist, or dermatologist. CRSwNP (init/reauth): Prescribed by or in consultation with an allergist/immunologist, otolaryngologist, or pulmonologist. IgE-Mediated Food Allergy (Init/Reauth): Prescribed by or in consultation with an allergist/immunologist. |
| **Coverage Duration** | Asthma,init:6mo,reauth:12mo. CSU,init:3mo,reauth:6mo. CRSwNP:12mo. Allergy,init:20wk,reauth:12mo |

| | |
|---|---|
| **Other Criteria** | Asthma (reauth): Patient demonstrates positive clinical response to therapy. Patient continues to be treated with ICS (eg, fluticasone, budesonide) with or without additional asthma controller medication (eg, LTRA [eg, montelukast], LABA [eg, salmeterol], LAMA [eg, tiotropium]) unless there is a contraindication or intolerance to these medications. Chronic Spontaneous Urticaria (CSU) (init): Diagnosis of CSU. Persistent symptoms (itching and hives) with a second generation H1 antihistamine (eg, cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist (eg, famotidine, cimetidine), leukotriene receptor antagonist (eg, montelukast), H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. CSU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline. Chronic Rhinosinusitis with Nasal polyps (CRSwNP) (init): Diagnosis of CRSwNP. Unless contraindicated, the patient has had an inadequate response to an intranasal corticosteroid (eg, fluticasone, mometasone). Used in combination with another agent for chronic rhinosinusitis with nasal polyps. CRSwNP (reauth): Patient demonstrates positive clinical response to therapy. Used in combination with another agent for chronic rhinosinusitis with nasal polyps. IgE-Mediated Food Allergy (Initial): One of the following: A) Both of the following: 1) Diagnosis of IgE Mediated Food Allergy as evidenced by one of the following: a) Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food, b) Positive food specific IgE (greater than or equal to 6 kUA/L), c) Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein, AND 2) Clinical history of IgE Mediated Food Allergy, OR B) Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods. Used in conjunction with food allergen avoidance. Baseline (pre-Xolair tx) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL. Dosing is according to serum total IgE levels and body weight. IgE-Mediated Food Allergy (Reauth): Patient demonstrates positive clinical response to therapy. Used in conjunction with food allergen avoidance. Dosing will continue to be based on body weight and pretreatment total IgE serum levels. |

# XOLREMDI (S)

**Products Affected**

- Xolremdi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Initial: Diagnosis of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome. Patient has genotype confirmed variant of CXCR4 as detected by an FDA-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Patient has an absolute neutrophil count (ANC) less than or equal to 500 cells/µL. |
| **Age Restrictions** | Initial: Patient is 12 years of age or older. |
| **Prescriber Restrictions** | Initial: Prescribed by or in consultation with one of the following: immunologist, hematologist, geneticist, or allergist. |
| **Coverage Duration** | Initial: 6 months, Reauth: 12 months |
| **Other Criteria** | Reauth: Patient demonstrates positive clinical response to therapy. |

# XOSPATA (S)

**Products Affected**

- Xospata

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of acute myeloid leukemia (AML). Disease is relapsed or refractory. Patient has a FMS-like tyrosine kinase (FLT3) mutation as determined by a U.S. Food and Drug Administration (FDA)-approved test (e.g., LeukoStrat CDx FLT3 Mutation Assay) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XPOVIO (S)

## Products Affected

- Xpovio
- Xpovio 100 Mg Once Weekly
- Xpovio 40 Mg Once Weekly
- Xpovio 40 Mg Twice Weekly
- Xpovio 60 Mg Once Weekly
- Xpovio 60 Mg Twice Weekly
- Xpovio 80 Mg Once Weekly
- Xpovio 80 Mg Twice Weekly

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Multiple Myeloma (MM), Diffuse large B-cell lymphoma (DLBCL): Diagnosis of one of the following: 1) DLBCL OR 2) Multiple Myeloma. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XTANDI (S)

**Products Affected**

- Xtandi

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-resistant or castration-recurrent prostate cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Metastatic castration-sensitive prostate cancer (M-CSPC): Diagnosis of metastatic castration-sensitive prostate cancer. Non-metastatic castrion-sensitive prostate cancer (nm-CSPC): Diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC). Patient has high-risk biochemical recurrence (BCR) defined by a PSA doubling time less than or equal to 9 months and one of the following: A) PSA values greater than or equal to 1 ng/mL if the patient had prior prostatectomy (with or without radiotherapy) OR B) PSA values at least 2 ng/mL above the nadir if the patient had prior radiotherapy only. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# XYREM (S)

## Products Affected

- Sodium Oxybate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | All uses (initial): Prescribed by or in consultation with one of the following: neurologist, psychiatrist, or sleep medicine specialist. |
| **Coverage Duration** | All uses (initial): 6 months. All uses (reauth): 12 months |
| **Other Criteria** | Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with therapy. |

# YUFLYMA (S)

## Products Affected

- Yuflyma 1-pen Kit
- Yuflyma 2-pen Kit
- Yuflyma 2-syringe Kit
- Yuflyma Cd/uc/hs Starter

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Minimum duration of a 3-month trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies at maximally tolerated doses: methotrexate, leflunomide, sulfasalazine. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Minimum duration of a 6-week TF/C/I to one of the following conventional therapies at maximally tolerated doses: leflunomide or methotrexate. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: actively inflamed joints, dactylitis, enthesitis, axial disease, or active skin and/or nail involvement. Plaque Psoriasis (PsO) (Initial): Diagnosis of moderate to severe chronic PsO. One of the following: at least 3% body surface area (BSA) involvement, severe scalp psoriasis, OR palmoplantar (ie, palms, soles), facial, or genital involvement. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Minimum duration of a one-month TF/C/I to one NSAID (eg, ibuprofen, naproxen) at maximally tolerated doses. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. One of the following: frequent diarrhea and abdominal pain, at least 10% weight loss, complications (eg, obstruction, fever, abdominal mass), abnormal lab values (eg, CRP), OR CD Activity Index (CDAI) greater than 220. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), methotrexate. Uveitis (initial): Diagnosis of non-infectious uveitis, classified as intermediate, posterior, or panuveitis. |
| **Age Restrictions** | N/A |

| | |
|---|---|
| **Prescriber Restrictions** | RA, AS, JIA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. PsO, HS (initial): Prescribed by or in consultation with a dermatologist. CD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist. |
| **Coverage Duration** | UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial): 6 mo, (reauth): 12 mo. |

| | |
|---|---|
| **Other Criteria** | Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. One of the following: greater than 6 stools per day, frequent blood in the stools, frequent urgency, presence of ulcers, abnormal lab values (eg, hemoglobin, ESR, CRP), OR dependent on, or refractory to, corticosteroids. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, azathioprine, corticosteroid (eg, prednisone), aminosalicylate [eg, mesalamine, olsalazine, sulfasalazine]. Hidradenitis suppurativa (HS) (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). RA, PJIA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline OR improvement in symptoms (eg, pain, stiffness, inflammation) from baseline. PsA (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: reduction in the total active (swollen and tender) joint count from baseline, improvement in symptoms (eg, pain, stiffness, pruritus, inflammation) from baseline, OR reduction in the BSA involvement from baseline. HS, Uveitis (Reauth): Patient demonstrates positive clinical response to therapy. PsO (Reauth): Patient demonstrates positive clinical response to therapy. AS (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by improvement from baseline for at least one of the following: disease activity (eg, pain, fatigue, inflammation, stiffness), lab values (erythrocyte sedimentation rate, C-reactive protein level), function, axial status (eg, lumbar spine motion, chest expansion), OR total active (swollen and tender) joint count. CD (Reauth): Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. UC (Reauth): For patients who initiated therapy within the past 12 weeks: Patient demonstrates clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on therapy for longer than 12 weeks: Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following: improvement in intestinal inflammation (eg, mucosal healing, improvement of lab values [platelet counts, erythrocyte sedimentation rate, C-reactive protein level]) from baseline, OR reversal of high fecal output state. |

# ZAVESCA (S)

## Products Affected

- Miglustat
- Yargesa

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. |
| **Age Restrictions** | Gaucher disease: Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | Gaucher disease: 12 months |
| **Other Criteria** | N/A |

# ZEJULA (S)

**Products Affected**

- Zejula

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZELBORAF (S)

## Products Affected

- Zelboraf

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by a U.S. Food and Drug Administration (FDA)-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | All indications: Approve for continuation of therapy. |

# ZOKINVY (S)

**Products Affected**

- Zokinvy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | One of the following: 1) Diagnosis of Hutchinson-Gilford Progeria Syndrome, OR 2) For treatment of processing-deficient Progeroid Laminopathies with one of the following: i) Heterozygous LMNA mutation with progerin-like protein accumulation OR ii) Homozygous or compound heterozygous ZMPSTE24 mutations. Patient has a body surface area of 0.39 m^2 and above. |
| **Age Restrictions** | Patient is 12 months of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | N/A |

# ZOLINZA (S)

**Products Affected**

- Zolinza

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZTALMY (S)

**Products Affected**

- Ztalmy

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Diagnosis of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD). Patient has a mutation in the CDKL5 gene. Trial and failure, contraindication, or intolerance to two formulary anticonvulsants (e.g., valproic acid, levetiracetam, lamotrigine). |
| **Age Restrictions** | Patient is 2 years of age or older. |
| **Prescriber Restrictions** | Prescribed by or in consultation with a neurologist. |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZURZUVAE (S)

**Products Affected**

- Zurzuvae

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Postpartum Depression (PPD): One of the following: A) Diagnosis of severe PPD or B) Both of the following: a) Diagnosis of mild to moderate PPD, and b) Trial and failure, contraindication, or intolerance to at least one oral SSRI or SNRI (e.g., escitalopram, duloxetine). Onset of symptoms in the third trimester or within 4 weeks of delivery. Prescriber attests that the patient has been counseled and has agreed to adhere to the following: Will follow instructions to not drive or operate machinery until at least 12 hours after taking each dose of Zurzuvae for the duration of the 14-day treatment course and that patients are informed that they may not be able to assess their own driving competence or the degree of driving impairment caused by Zurzuvae. |
| **Age Restrictions** | PPD: Patient is 18 years of age or older. |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 14 days |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZYDELIG (S)

**Products Affected**

- Zydelig

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZYKADIA (S)

**Products Affected**

- Zykadia TABS

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test or a test performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | 12 months |
| **Other Criteria** | Approve for continuation of prior therapy. |

# ZYTIGA (PREFERRED) (S)

## Products Affected

- Abiraterone Acetate

| PA Criteria | Criteria Details |
|---|---|
| **Indications** | All Medically-accepted Indications. |
| **Off-Label Uses** | N/A |
| **Exclusion Criteria** | N/A |
| **Required Medical Information** | Castration-Resistant Prostate Cancer (CRPC): Diagnosis of castration-resistant (chemical or surgical) or recurrent prostate cancer. Castration-Sensitive Prostate Cancer (CSPC): Diagnosis of castration-sensitive prostate cancer. |
| **Age Restrictions** | N/A |
| **Prescriber Restrictions** | N/A |
| **Coverage Duration** | CRPC, CSPC: 12 months |
| **Other Criteria** | Approve for continuation of prior therapy |

# PART B VERSUS PART D

## Products Affected

- Abelcet
- Acyclovir Sodium INJ 50MG/ML
- Albuterol Sulfate NEBU 0.083%, 2.5MG/0.5ML
- Aminosyn II INJ 107.6MEQ/L; 1490MG/100ML; 1527MG/100ML; 1050MG/100ML; 1107MG/100ML; 750MG/100ML; 450MG/100ML; 990MG/100ML; 1500MG/100ML; 1575MG/100ML; 258MG/100ML; 405MG/100ML; 447MG/100ML; 1083MG/100ML; 795MG/100ML; 50MEQ/L; 600MG/100ML; 300MG/100ML; 750MG/100ML
- Amphotericin B INJ
- Amphotericin B Liposome
- Aprepitant CAPS
- Astagraf XL
- Azathioprine TABS 50MG
- Budesonide SUSP
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Engerix-b
- Envarsus Xr
- Everolimus TABS 0.25MG, 0.5MG, 0.75MG, 1MG
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf CAPS 100MG, 25MG
- Gengraf SOLN
- Heplisav-b
- Hyperhep B
- Imovax Rabies (h.d.c.v.)
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Mycophenolate Mofetil CAPS
- Mycophenolate Mofetil SUSR
- Mycophenolate Mofetil TABS
- Mycophenolic Acid Dr
- Nabi-hb INJ 312UNIT/ML
- Nutrilipid
- Ondansetron Hcl SOLN
- Ondansetron Hydrochloride TABS
- Ondansetron Odt TBDP 4MG, 8MG
- Pentamidine Isethionate INHALATION SOLR
- Plenamine INJ 147.4MEQ/L; 2.17GM/100ML; 1.47GM/100ML; 434MG/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 749MG/100ML; 1.04GM/100ML; 1.18GM/100ML; 749MG/100ML; 1.04GM/100ML; 894MG/100ML; 592MG/100ML; 749MG/100ML; 250MG/100ML; 39MG/100ML; 960MG/100ML
- Prehevbrio
- Prograf PACK
- Rabavert
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus SOLN
- Sirolimus TABS
- Tacrolimus CAPS
- Tobramycin NEBU 300MG/5ML

## Details

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

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